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(71) Applicant *(for all designated States except US)*: **PROXIMARE, INC.** [US/US]; 1441 Perry Avenue, Salt Lake City, Utah 84103 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **WHISENANT, Brian, K.** [US/US]; 1441 Perry Avenue, Salt Lake City, Utah 84103 (US). **DAVIS, Clark, C.** [US/US]; 4564 Wallace Lane, Holladay, Utah 84119 (US). **EDMISTON, Daryl** [US/US]; 754 West Marsh Cove, Draper, Utah 84020 (US).

(74) Agent: **LAURENCE, Kevin, B.**; One Utah Center, 201 So. Main Street, Suite 1100, Salt Lake City, Utah 84111 (US).

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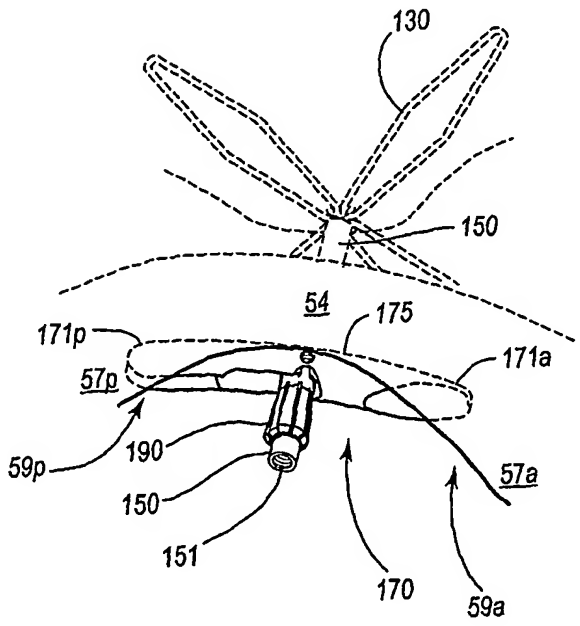
(54) Title: PATENT FORAMEN OVALE (PFO) CLOSURE DEVICES, DELIVERY APPARATUS AND RELATED METHODS AND SYSTEMS



(57) Abstract: Devices for closure of a patent foramen ovale, apparatus for delivery of the closure device and methods and systems for closing a patent foramen ovale are disclosed.

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PATENT FORAMEN OVALE (PFO) CLOSURE DEVICES, DELIVERY APPARATUS AND RELATED METHODS AND SYSTEMS

Technical Field

[0001] The present invention relates generally to a patent foramen ovale ("PFO") in a mammalian heart. More specifically, the present invention relates to apparatus, methods, and systems for closure of a septal defect between the right and left atriums of a patient's heart.

Brief Description of the Drawings

[0002] Understanding that drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with specificity and detail through the use of the accompanying drawings. The drawings are listed below.

[0003] FIG. 1A is a cross-sectional view of a heart.

[0004] FIG. 1B is an enlarged cross-section view of septum primum and the septum secundum and a PFO tunnel between the septum primum and the septum secundum.

[0005] FIG. 1C is a perspective view of the septum secundum with the tunnel and the septum primum shown in phantom.

[0006] FIG. 2 is a plan view of an embodiment of a PFO closure device 100.

[0007] FIG. 3A is an exploded perspective view of PFO closure device 100 and components of a delivery apparatus 200.

[0008] FIG. 3B is an assembled side view of PFO closure device 100 and components of delivery apparatus 200 shown in FIG. 3A.

[0009] FIG. 4A is a perspective view of PFO closure device 100 while still attached via a threaded detachment tip 210 (not shown in FIG. 4A) to a stem 220. Stem 220 and threaded detachment tip 210 comprises a left atrial anchor (LAA) advancer 230.

[0010] FIG. 4B is a cross-sectional view taken at cutting line 4B-4B which shows retainers 140 within anchor connector 150 and threaded detachment tip 210 (not shown in FIG. 4A) while it is still within anchor connector 150 for delivery.

[0011] FIG. 4C is a side view of right atrial anchor 170 attached to pivot collar 190 before pivot collar 190 has been pushed fully onto anchor connector 150 and off of stem 220.

[0012] FIG. 4D is a top view of right atrial anchor 170 attached to pivot collar 190 before pivot collar 190 has been pushed fully onto anchor connector 150 and off of stem 220.

[0013] FIG. 4E is a cross-sectional view of right atrial anchor 170 attached to pivot collar 190 taken on cutting line 4E—4E. FIG. 4E also provides a perspective view of stem 220 as pivot collar 190 is positioned around stem 220 in a configuration which permits pivot collar 190 to be glided on stem 220.

[0014] FIG. 4F is an enlarged perspective view of pivot collar 190.

[0015] FIG. 4G is a bottom view of pivot collar 190 taken from line 4G—4G.

[0016] FIG. 5A is a perspective view of catheter 250 and a cross-sectional view of PFO 50 which depicts an initial step in the method of delivering PFO closure device 100. FIGS. 5B-5P depict subsequent steps.

[0017] FIG. 5B is a cross-sectional view of delivery apparatus 200 positioned at PFO 50 to deploy left atrial anchor 130 of closure device 100.

[0018] FIG. 5C is perspective view of left atrial anchor 130 as it is being deployed out of catheter 250.

[0019] FIG. 5D is a cross-sectional view of left atrial anchor 130 of closure device 100 deployed into left atrium 40.

[0020] FIG. 5E is perspective view from within left atrium 40 of left atrial anchor 130 of closure device 100 after it has been deployed into left atrium 40.

[0021] FIG. 5F is a cross-sectional view of left atrial anchor 130 of closure device 100 being pulled against septum primum 52 and septum secundum 54 in the left atrium 40.

[0022] FIG. 5G is perspective view from within left atrium 140 of left atrial anchor 130 of closure device 100 being pulled against septum primum 52 and septum secundum 54 in the left atrium 40.

[0023] FIG. 5H is a cross-sectional view of right atrial anchor 170 of closure device 100 being deployed in right atrium 30.

[0024] FIG. 5I is perspective view from within right atrium 30 of right atrial anchor 170 after deployment and ready for clockwise rotation by right atrial anchor (RAA) advancer 270.

[0025] FIG. 5J is a cross-sectional view of right atrial anchor 170 of closure device 100 being deployed in right atrium 30.

[0026] FIG. 5K is perspective view from within right atrium 30 of right atrial anchor 170 positioned under the overhang of septum secundum 54.

[0027] FIG. 5L is a cross-sectional view of right atrial anchor 170 being advanced on anchor connector 150 toward left atrial anchor 130.

[0028] FIG. 5M is perspective view from within right atrium 30 of right atrial anchor 170 as positioned on anchor connector 150 by right atrial anchor (RAA) advancer 270.

[0029] FIG. 5N is a cross-sectional view of closure device 100 and delivery apparatus 200 after removal of left atrial anchor (LAA) advancer 230.

[0030] FIG. 5O is perspective view from within right atrium 30 of closure device 100 and right atrial anchor (RAA) advancer 270 of delivery apparatus 200 after removal of left atrial anchor (LAA) advancer 230.

[0031] FIG. 5N is a cross-sectional view of closure device 100 and delivery apparatus 200 after removal of right atrial anchor (LAA) advancer 270 and catheter 250.

[0032] FIG. 5P is perspective view from within right atrium 30 of closure device 100 positioned in PFO 50 after removal of delivery apparatus 200.

[0033] FIG. 6A is a plan view of an embodiment of a PFO closure device 100'.

[0034] FIG. 6B is an assembled side view of PFO closure device 100' and components of delivery apparatus 200'.

[0035] FIG. 6C is an exploded perspective view of right atrial anchor 170' and right atrial anchor (RAA) retainer 190', also referred to herein as a pivot collar 190'.

[0036] FIGS. 6D is a cross-sectional view taken along cutting line 6D—6D which depicts pivot collar 190' as positioned in right atrial anchor 170'.

[0037] FIG. 6E is a perspective view of closure device 100' (with right atrial anchor 170' shown in a cross-sectional view) and components of delivery apparatus 200 including coupler 290'.

[0038] FIG. 6F is a perspective view of closure device 100' (with right atrial anchor 170' shown in a cross-sectional view) and coupler 290' engaging pivot members 194' of pivot collar 190'.

[0039] FIGS. 6G is a cross-sectional view taken along cutting line 6G—6G which depicts coupler 290' engaging pivot members 194' of pivot collar 190'.

[0040] FIG. 7A is a perspective view depicting another embodiment of a right atrial anchor at 170a.

[0041] FIG. 7B is a perspective view depicting another embodiment of a right atrial anchor at 170b.

[0042] FIG. 7C is a perspective view depicting another embodiment of a right atrial anchor at 170c.

[0043] FIG. 7D is a plan view depicting another embodiment of a right atrial anchor at 170d.

[0044] FIG. 7E is a side view of the embodiment of right atrial anchor 170d shown in FIG. 7E.

[0045] FIG. 8A is perspective view from within right atrium 30 of closure device 100 positioned in PFO 50 with both ends of right atrial anchor 170 positioned within pockets 59a and 59p.

[0046] FIG. 8B is perspective view from within right atrium 30 of closure device 100 positioned in PFO 50 with one end of right atrial anchor 170 positioned within pocket 59p.

[0047] FIG. 8C is perspective view from within right atrium 30 of closure device 100 positioned in PFO 50 with both ends 171 of right atrial anchor 170a positioned within pockets 59a and 59p.

[0048] FIG. 8D is perspective view from within right atrium 30 of closure device 100 positioned in PFO 50 with one end 171 of right atrial anchor 170a positioned within pocket 59p.

[0049] FIG. 9 is plan and cross-sectional view of another embodiment of a left atrial anchor as identified at 130'.

[0050] FIG. 10 is perspective view of another embodiment of a left atrial anchor as identified at 130".

[0051] FIG. 11 is cross-sectional view of another embodiment of a left atrial anchor as identified at 130'".

[0052] FIG. 12A is a cross-sectional view of another embodiment of a closure device 100a having a left atrial anchor 130a and another embodiment of a delivery apparatus 200" having a left atrial anchor (LAA) advancer 230".

[0053] FIG. 12B provides a perspective view of left atrial anchor 130a as depicted in FIG. 12A during deployment and a cross-section view of catheter 250" to show right atrial anchor (LAA) advancer 270".

[0054] FIG. 12C provides a perspective view of left atrial anchor 130a as compressed in a left atrium and right atrial anchor 170" as positioned in the right atrium by right atrial anchor (LAA) advancer 270".

[0055] FIG. 13A is a plan view of left atrial anchor 130a shown in FIGS. 12A-12C.

[0056] FIG. 13B is a plan view of another embodiment of a left atrial anchor as identified at 130b.

[0057] FIG. 13C is a plan view of another embodiment of a left atrial anchor as identified at 130c.

[0058] FIG. 13D is a plan view of another embodiment of a left atrial anchor as identified at 130d.

[0059] FIG. 13E is a plan view of another embodiment of a left atrial anchor as identified at 130e.

[0060] FIG. 13F is a plan view of another embodiment of a left atrial anchor as identified at 130f as combined with web 122f.

[0061] FIG. 14A is an enlarged cross-sectional view of the joint identified at 135a.

[0062] FIG. 14B is an enlarged cross-sectional view of the joint identified at 135b.

[0063] FIG. 14C is an enlarged cross-sectional view of the joint identified at 135c.

[0064] FIG. 14D is a side view of left atrial anchor 130d.

[0065] FIG. 15A is a plan view of web 122 for combination with left atrial anchor members of left atrial anchor 130e.

[0066] FIG. 15B is a plan view of web 122' for combination with left atrial anchor members of left atrial anchor 130e.

[0067] FIG. 15C is a side view of left atrial anchor 130f and anchor connector 150f.

Index of Elements Identified in the Drawings

[0068] Elements of the heart 10 are shown in FIGS. 1A-1C. Some of these elements are also shown in one or more of or are discussed with reference FIGS. 5A-5Q, 8A-8D, and 11. These elements include:

15	superior vena cava
25	inferior vena cava
30	right atrium
35	tricuspid valve
40	left atrium
45	bicuspid valve
50	PFO
52	septum primum
53	superior aspect
54	septum secundum
56a	anterior merger point
56p	posterior merger point
57a	anterior portion
57p	posterior portion
58	tunnel
59a	anterior pocket
59p	posterior pocket
60	right ventricle
70	interventricular septum
75	pulmonary veins

80 left ventricle

85 aorta

99 delivery path

[0069] The elements listed below are components of patent foramen ovale (PFO) closure device 100 or other embodiments including 100', 100", 100"' and 100a. Note that all features or subcomponents of components even those which relate only to a particular embodiment are listed below without reference to the particular embodiment. For example, left atrial anchors 130a-f and right atrial anchors 170' and 170a-d include certain features and subcomponents which are unique to the particular embodiment, however, they are generically included in this list and are not individually listed. The following elements are shown in one or more of or are discussed with reference to FIGS. 2, 3A-3B, 4A-4G, 5B-5Q, 6A-6G, 7A-7C, 8A-8D, 9, 10, 11, 12A-12C, 13A-13F, 14A-14D, and 15A-15C. These elements include:

120 mesh

122 web

123 arm link

124 perimeter link

125 inset link

130 left atrial anchor

132 anchor member

133 flex point

134 tips

135 joints (referenced to LAA 130a-c)

138 first center feature (referenced to LAA 130a and LAA 130d)

139 second center feature (referenced to LAA 130a and LAA 130d)

140	left atrial anchor retainer
150	anchor connector
151	threads
152	stop
153	end (referenced to anchor connector 150a)
155	retention holes
157	right atrial anchor (RAA) end of anchor connector 150
158	coating
162	non-resorbable components (referenced to RAA 170b-c)
164	resorbable components (referenced to RAA 170b-c)
166	notches (referenced to RAA 170b-c)
168	torque groove
170	right atrial anchor
171a	anterior end of right atrial anchor 170
171p	posterior end of right atrial anchor 170
172a	stem groove of anterior end 171a
172p	stem groove of posterior end 171p
173a	stem chamber of anterior end 171a
173p	stem chamber of posterior end 171p
174	hole
175	top surface or contact surface
176a	flat portion
176p	rounded portion

177 concave portion

178 pivot groove

179 pivot chamber

180 loop or flex point or region

184 opening in right atrial anchor

190 right atrial anchor (RAA) retainer, pivot collar or locking arm

191 groove

192 band (referenced with pivot collar 190')

194 pivot members

195 ferrule (referenced with pivot collar 190')

196 body portion

199 retention pawls

[0070] The elements listed below are components of delivery apparatus 200, 200', 200" or other embodiments. The following elements are shown in one or more of or discussed with reference to FIGS. 3A-3B, 4A, 4E, 5A-5O, 6B, 6E-6G, and 12A including:

210 threaded detachment tip

212 threads

220 stem

230 left atrial anchor (LAA) advancer

250 catheter

270 right atrial anchor (RAA) advancer

280 stem

290 coupler

294 torque feature

Detailed Description of Preferred Embodiments

[0071] FIGS. 1A-1C depict various views of a heart. Heart 10 is shown in a cross-section view in FIG. 1A. In a normal heart, the right atrium 30 receives systemic venous blood from the superior vena cava 15 and the inferior vena cava 25 and then delivers the blood via the tricuspid valve 35 to the right ventricle 60. However, in heart 10, there is a septal defect between right atrium 30 and left atrium 40 of a patient's heart which is referred to as a patent foramen ovale ("PFO"). The PFO, which is an open flap on the septum between the heart's right and left atria, is generally identified at 50. In a normal heart, left atrium 40 receives oxygenated blood from the lungs 40 via pulmonary veins 75 and then delivers the blood to the left ventricle 80 via the bicuspid valve 45. However, in heart 10 some systemic venous blood also passes from right atrium 30 through PFO 50, mixes with the oxygenated blood in left atrium 40 and then is routed to the body from left ventricle 80 via aorta 85.

[0072] During fetal development of the heart, the interventricular septum 70 divides right ventricle 60 and left ventricle 80. In contrast, the atrium is only partially partitioned into right and left chambers during normal fetal development as there is a foramen ovale. When the septum primum 52 incompletely fuses with the septum secundum 54 of the atrial wall, the result is a PFO, such as the PFO 50 shown in FIGS. 1A-1C, or an atrial septal defect referred to as an ASD.

[0073] FIG. 1C provides a view of the crescent-shaped, overhanging configuration of the typical septum secundum 54 from within right atrium 30. Septum secundum 54 is defined by its inferior aspect 55, corresponding with the solid line in FIG. 1C, and its superior aspect 53, which is its attachment location to septum primum 52 as represented by the phantom line. Septum secundum 54 and septum primum 52 blend together at the ends of septum secundum 54; these anterior and posterior ends are referred to herein as "merger points" and are respectively identified at 56a and 56p.

The length of the overhang of septum secundum 54, the distance between superior aspect 53 and inferior aspect 55, increases towards the center portion of the septum secundum as shown. A tunnel 58 is defined by portions of septum primum 52 and septum secundum 54 between the merger points 56a and 56p which have failed to fuse. The tunnel is often at the apex of the septum secundum as shown. When viewed within right atrium 30, the portion of septum secundum 54 to the left of tunnel 58, which is referred to herein as the posterior portion 57p of the septum secundum, is longer than the portion of the septum secundum 54 to the right of tunnel 58, which is referred to herein as the anterior portion 57a of the septum secundum. In addition to being typically longer, the left portion also typically has a more gradual taper than the right portion, as shown. The area defined by the overhang of the anterior portion 57a of septum secundum 54 and the septum primum 52 and extending from the anterior merger point 56a toward tunnel 58 is an anterior pocket 59a. Similarly, the area defined by the overhang of the posterior portion 57p of septum secundum 54 and the septum primum 52 and extending from the posterior merger point 56p toward tunnel 58 is a posterior pocket 59p.

[0074] The invention described hereinafter relates to a closure device, a delivery apparatus, methods, and systems for closure of a PFO. FIG. 2 depicts one embodiment of a closure device at 100. FIGS. 3A-3B depict closure device 100 and an embodiment of a delivery apparatus 200.

[0075] Closure device 100 comprises a left atrial anchor 130 and a right atrial anchor 170. In the embodiment of the closure device shown in FIG. 2, left atrial anchor 130 and right atrial anchor 170 are coupled together via an anchor connector 150. Left atrial anchor 130 is secured to anchor connector 150 via two left atrial anchor (LAA) retainers 140. While the components described above are separate, several of these components may alternatively be integral. For example, in another embodiment, left atrial anchor 130, retainer 140 and/or anchor coupler 150 may be integral. Right atrial anchor 170 is secured to anchor connector 150 by a right atrial anchor (RAA) retainer. The embodiment of right atrial anchor (RAA) retainer identified at 190 is referred to herein as a pivot collar.

[0076] Anchor connector may alternatively be coated with a coating 158 as may left atrial anchor 130, right atrial anchor 170 and any other component of closure device 100 to facilitate closure of PFO 50. Such coatings may be applied to promote occlusion of tunnel 58 and endothelial growth while minimizing thrombosis and embolization. For example, a coating of bioresorbable polymers may be applied which facilitates closure of tunnel 58. Examples of suitable bioresorbable polymers include polycaprolactones, polyorthoesters, polylactide, polyglycolide and copolymers of these polymers. An example of a suitable copolymer is polylactide and polyglycolide. In addition to polymers, drug eluting compositions, proteins and growth factors may also be applied as coatings. Examples of suitable proteins and growth factors include elastin, fibronectin, collagen, laminin, basic fibroblast growth factor, platelet-derived growth factor. The coating may be cellular or foamed or may be more dense as needed. The material used for the coating may depend on the particular component of closure device 100 being coated. For example, elastin is useful for coating left atrial anchor 130 and right atrial anchors as it is not aggressive for tissue growth. Anchor connector 150 may be wrapped with a foam material, fuzzy bioresorbable thread or any other material which assists in facilitating the closure of tunnel 58.

[0077] By coating components of closure device 100 such as left atrial anchor 130, anchor connector 150 and right atrial connector 170, tissue growth can be promoted at the points of contact of each of these three components in three regions or planes. Note that the components of the closure device may also be formed entirely from the materials listed above for coatings.

[0078] FIG. 3A provides an exploded perspective view of closure device 100 and some components of delivery apparatus 200. FIG. 3B provides a cross-sectional view of the same components. Components of delivery apparatus 200 shown in FIGS. 3A-3B include a left atrial anchor (LAA) advancer 230 for advancing left atrial anchor 130, a right atrial anchor (RAA) advancer 270 for advancing right atrial anchor 170 and catheter 250. Left atrial anchor (LAA) advancer 230 comprises a stem 220 which is fixedly or integrally coupled to a threaded detachment tip 210. Right atrial anchor (RAA)

advancer 270 comprises a stem 280 and a coupler 290. Left atrial anchor (LAA) advancer 230 pass through right atrial anchor (RAA) advancer 270.

[0079] FIGS. 4A-4G show additional features of closure device 100 particularly, right atrial anchor 170. The functions of these features are best understood with reference to FIGS. 5A-5P.

[0080] FIG. 4A provides a perspective view of closure device 100 with anchor connector 150 still attached to stem 220 of left atrial anchor (LAA) advancer 230. Right atrial anchor 170 has not yet been advanced into its final position on the right atrial anchor (RAA) end 157 of anchor connector 150. Hole 155 in end 157 of anchor connector 150 are shown in FIG. 4A ready to receive retention pawls 199 of pivot collar 190, which is more generally referred to as a right atrial anchor (RAA) retainer.

[0081] FIG. 4B provides a cross-section view of anchor connector 150 taken at cutting line 4B-4B. FIG. 4B shows retainers 140 within anchor connector 150 and a coating 158 on anchor connector 150.

[0082] FIG. 4C is a side view of right atrial anchor 170 attached to pivot collar 190 before pivot collar 190 has been pushed fully onto anchor connector 150 and off of stem 220. FIG. 4D is a top view of right atrial anchor 170 attached to pivot collar 190 in the same position as is shown in FIG. 4C. Fig. 4E provides a cross-sectional view of right atrial anchor 170 taken on cutting line 4E—4E, right atrial anchor 170 is in the same position as FIGS. 4C-4D on stem 220 after being rotated. FIG. 4E also provides a perspective view of stem 220 as pivot collar 190 is positioned around stem 220 in a configuration which permits pivot collar 190 to be glided on stem 220.

[0083] Right atrial anchor 170 has two opposing ends which are respectively adapted to be positioned in anterior pocket 59a and posterior pocket 59p. The opposing end identified at 171a may be placed in anterior pocket 59a or adjacent to the anterior portion 57a of septum secundum 54. Similarly, the opposing end of right atrial anchor 170 identified at 171p may be placed in posterior pocket 59p or adjacent to the posterior anterior portion 57p. Right atrial anchor is relatively symmetrical so that end 171p or end 171a can be positioned in either posterior pocket 59p or anterior pocket 59a. Accordingly, the use of the designations "a" and "p" to designate an eventual position

with either an anterior or posterior orientation does not indicate that either end 171a or end 171p must be positioned to have respective anterior and posterior orientations.

[0084] To permit right atrial anchor 170 to be easily moved within a catheter, right atrial anchor 170 has three chambers which are adapted to fit around pivot collar 190, anchor connector 150 and stem 220. A stem groove is formed in the two opposing ends of right atrial anchor 170 as identified at 172a and 172p which each respectively defined a stem chamber 173a and 173p. Pivot collar 190 has pivot members 194 which are received within holes 174 to permit right atrial anchor to pivot with respect to pivot collar 190. Right atrial anchor 170 has a pivot groove 178 which defines a pivot chamber 179. In this embodiment, the chambers described above allow relatively concentric movement of right atrial anchor 170 with respect to catheter 250 shown in FIG. 5B, anchor connector 150 and stem 220.

[0085] Right atrial anchor 170 has a top surface 175 which has a convex shape. The convex shape of top surface 175 permits optimal anatomical conformance with the shape of septum secundum 54. Note that the shape of surface 175 on either side of pivot groove 178 is essentially the same to permit right atrial anchor to oriented with ends 171a and 171p respectively positioned adjacent to portions 57p and 57a or vice versa. Right atrial anchor has a flat portion 176a opposite a rounded portion 176p at its bottom surface. Flat portion 176a provides for an optimal fit within catheter 250. The bottom surface includes a concave portion 177 between flat portion 176a and rounded portion 176p. Concave portion 177 is shaped to minimize the size of right atrial anchor 170.

[0086] Right atrial anchor 170 has a torque groove 168 which is adapted to fit in a mated with a complimentary torque feature 194. The interaction of torque groove 168 and torque feature 194 to rotate and move right atrial anchor 170 is described below with reference to FIGS. 5I-5O. Another embodiment of a torque feature for rotation and movement of a right atrial anchor is described below with reference to FIGS. 6A-6G.

[0087] Details of pivot collar 190 can be easily seen in the enlarged cross-sectional view of FIG. 4F and the view of pivot collar provided by FIG. 4G which is taken along line 4G—4G. Note that another embodiment of a right atrial anchor (RAA) retainer identified

at 190' is discussed below in relation to FIG. 6C. As mentioned above, pivot collar 190 has pivot members 194 which are received within holes 174 to permit right atrial anchor to pivot with respect to pivot collar 190. Pivot members 194 extend from body portion 196. A plurality of arms 198 extend from body portion 196. Each arm 198 has a retention pawl 199. As mentioned above, retention pawls 199 enter retention hole 155 of anchor connector 150 to secure pivot collar 190 to anchor connector 150.

[0088] FIGS. 5A-5P depict one method for delivering closure device 100 to PFO 50 via delivery apparatus 200 and deploying closure device 100. Steps involved in recapturing closure device 100 are shown in FIGS. 6A-6G.

[0089] Catheter 250 is introduced to PFO 50 via delivery path 99 which is identified in FIGS. 1A-1C. Catheter 250 is a long somewhat flexible catheter or sheath introduced into a vein such as the femoral vein and routed up to the right atrium of a patient's heart. The catheter may be tracked over a guide wire that has been advanced into the heart by a known methodology. After catheter 250 is introduced into the heart via inferior vena cava 25, catheter 250 is positioned at right atrium 30 in front of the interatrial communication or PFO, and then through tunnel 58. Once the distal end of 252 of catheter 250 is positioned at the end of tunnel 58 as shown in FIGS. 5A-5B or extends beyond tunnel 58, left atrial anchor 130 is deployed as shown in FIG. 5D.

[0090] FIG. 5B provides a cross-sectional view of closure device 100 and delivery apparatus 200 just before left atrial anchor 130 is pushed out of catheter 250 and deployed into left atrium 40. As indicated above, left atrial anchor (LAA) advancer 230, more particularly stem 220 and threaded detachment tip 210, move within right atrial anchor (RAA) advancer 270, more particularly stem 280 and coupler 290, to advance left atrial anchor 130 within catheter 250.

[0091] FIG. 5C depicts left atrial anchor 130 just before deployment and FIG. 5D depicts left atrial anchor 130 after deployment. As provided below, the left atrial anchor may have many different configurations which permit it to fit within the catheter, either by being rotatably or pivotally aligned with the axis of the catheter or by being sufficiently flexible to fit within the catheter in a compressed and/or flexed state. The state in which a left atrial anchor is within the catheter will be referred to herein as a delivery

configuration. The state in which an anchor is outside of the catheter and has been pivoted, rotated, flexed, expanded, or otherwise put in position to be placed at the PFO site will be referred to herein as a deployed configuration.

[0092] Depending on the particular embodiment of left atrial anchor, in deploying the left atrial anchor from the catheter, it will be expanded, pivoted, or rotated to extend once out of the catheter. The embodiment of the left atrial anchor depicted in FIG. 5D expands and pivots from the delivery configuration to a deployed configuration. Left atrial anchor 130 may be formed from any suitable material such as coiled metal, coiled polymer or a solid core of metal or plastic wrapped with metal or polymer coil. For example, left atrial anchor may be formed from super elastic nickel/titanium or nitinol. It may have a single strand core or a core with multiple strands. The core may be wrapped with metal wire formed from a dense biocompatible metal such as platinum, platinum/tungsten alloy, platinum/iridium alloy, or platinum/iridium/rhodium alloy to increase the radio-opacity of the left atrial anchor. Utilizing a multiple strand core permits the left atrial anchor to have lower bending stiffness and better memory compared with a left atrial anchor formed with a single strand having approximately the same cross-sectional area as the multiple strands.

[0093] FIG. 5E shows the appearance of left atrial anchor 130 from within left atrium 40 once left atrial anchor 130 has been deployed. Catheter 250 is shown extending beyond tunnel 58.

[0094] FIGS. 5F-5G show left atrial anchor being pulled proximally and positioned proximate to the PFO. For embodiments such as left atrial anchor 130, the left atrial anchor pivots at or near its center. This pivoting motion permits the left atrial anchor to conform to the surfaces of the septum secundum and the septum primum. Once left atrial anchor 130 is pivoted at an angle with respect to the axis of the anchor connector 150, left atrial anchor 130 is pulled flush against septum secundum 54 and septum primum 52. As explained above, each anchor member 132 is angled. More particularly, each anchor member 132 is bowed such that there is a flex point 133 along its length. Pulling left atrial anchor 130 flush against septum secundum 54 and septum primum 52 flattens anchor members 132 of left atrial anchor 130 and enables left atrial

anchor 130 to push against septum secundum 54 and septum primum 52 when closure device 100 is finally positioned. Note that tips 134 of each anchor member 132 remain angled slightly away from septum secundum 54 and septum primum 52 even after anchor members 132 are flattened to minimize trauma to septum secundum 54 and septum primum 52.

[0095] FIG. 5G depicts left atrial anchor 130 with two anchor members 132 of the left atrial anchor positioned against the septum primum of the heart and the other two anchor members 132 positioned against the septum secundum of the heart. In addition to a left atrial anchor with four anchor members, other configurations permit at least one anchor member 132 to be positioned against the septum primum of the heart while at least one other anchor member is positioned against the septum secundum of the heart such that the left atrial anchor remains positioned in the left atrium. For example, the left atrial anchor may have two or three anchor members or more than four anchor members. Examples of other shapes are described below in reference to FIGS. 9-11, 12A-12C, 13A-13I and 14A-14D.

[0096] Right atrial anchor 170 can be seen in its delivery configuration rotated within catheter 250 in FIG. 5F. Right atrial anchor 170 is deployed by advancing it with respect to catheter 250 by urging right atrial anchor (RAA) advancer 270 against right atrial anchor 170. Once outside of catheter 250 as shown in FIG. 5H, right atrial anchor 170 pivots into a deployed configuration such that it extends perpendicular to, or at least at an angle with respect to catheter 250. Note that at least one anchor member 132 is in a different plane relative to another anchor member 132.

[0097] FIG. 5I shows right atrial anchor 170 being rotated clockwise. Rotation of right atrial anchor 170 is achieved by rotating stem 280 of right atrial anchor (LAA) advancer 270. Left atrial anchor 130 and right atrial anchor 170 are not brought into a locked configuration until after right atrial anchor 170 is positioned. As right atrial anchor 170 is rotated, posterior end 171p tucks under the overhang of posterior portion 57p of septum secundum 54 and in posterior pocket 59p. The posterior end of a typical septum secundum has a deeper pocket than the anterior portion of a typical septum secundum. The deeper pocket of the typical posterior end makes it easier to position an end of the

right atrial anchor than under the anterior portion. Note that while FIGS. 5J-5Q depict or are described in reference to placement of the ends of right atrial anchor 170 into pocket 59a and pocket 59p at the anterior and posterior portions, closure device 100 also effectively closes a PFO when only one end of right atrial anchor 170 is positioned within pocket 59p and the other end is positioned on top of anterior portion 57a instead of in pocket 59a as discussed below with reference to FIG. 8B and FIG. 8D.

[0098] FIG. 5J depicts right atrial anchor positioned with its top surface 175 directed toward tunnel 58. FIG. 5K shows right atrial anchor 170 with its posterior end 171p partially under the overhanging posterior portion 57p of septum secundum in posterior pocket 59p and its anterior end 171a partially under the overhanging anterior portion 57a of septum secundum 54 in anterior pocket 59a.

[0099] In FIG. 5L, right atrial anchor 170 is shown after being driven toward left atrial anchor 130 on anchor connector 150 by right atrial anchor (RAA) advancer 270. Advancement of right atrial anchor 170 on anchor connector 150 enables retention pawls 199 of right atrial anchor (RAA) retainer 190 to enter retention hole 155 of anchor connector 150 so that right atrial anchor (RAA) retainer 190 is secured to anchor connector 150. Once retainer 190 locks with connector 150, right atrial anchor 170 becomes positioned further under septum secundum 54, as shown in FIG. 5M. More particularly, FIG. 5M shows right atrial anchor 170 with its posterior end 171p fully under the overhanging posterior portion 171p of septum secundum 54 in posterior pocket 59pand its anterior end 171a fully under the overhanging anterior portion 57a of septum secundum 54 in anterior pocket 59a. With reference to FIG. 3A and FIG. 4A, note that there may be only one hole 155 while there is a plurality of retention pawls 199. This ratio and the relative widths of the hole 155 and retention pawls 199 ensures that at least one pawl 199 will be engaged in hole 155.

[00100] The sequence of steps described above with reference to FIGS. 5H-5M, indicates that the right atrial anchor 170 is first rotated clockwise into position and then right atrial anchor 170 is advanced toward left atrial anchor 130. However, these steps may also be achieved in manner which involves simultaneous clockwise rotation and advancement of right atrial anchor 170. Simultaneous rotation and advancement may

involve a transition from a combination of rotation and advancement to just advancement.

[00101] FIGS. 5N-5O shows catheter 250 after removal of left atrial anchor (LAA) advancer 230. Left atrial anchor (LAA) advancer 230 can be removed after right atrial anchor 170 has been driven forward and locked with anchor connector 150 as described with reference to FIG. 5H-5M. Removal of left atrial anchor (LAA) advancer 230 is achieved by rotating stem 220 counterclockwise while maintaining tension on stem 220 and holding stem 280 secure so that threads 212 of tip 210 are no longer engaged by threads 151 of anchor connector 150. Once right atrial anchor 170 and left atrial anchor 130 have been deployed and properly positioned in the heart against the septum primum and septum secundum, as discussed above, the deployed anchors may then be detached from the remainder of the device. More particularly, after left atrial anchor (LAA) advancer 230 has been removed, then right atrial anchor advancer 270 is removed from catheter 250.

[00102] FIG. 5P-5Q depict closure device 100 in a closure position relative to PFO 50 after delivery apparatus 200 has been removed. Following deployment and positioning of the anchors, the right and left atrial anchors are left to remain in the heart on opposite sides of the PFO. The tissue at the PFO is compressed between left atrial anchor 130 and right atrial anchor 170 via anchor connector. This configuration permits closure device 100 to remain in the heart in a stable configuration and facilitate closure of the PFO.

[00103] FIGS. 6A-6F depict another embodiment of closure device which is identified as 100' and another embodiment of delivery apparatus which is identified as 200'. The components of closure device 100' which are different from closure device 100 include anchor connector 150', right atrial anchor 170, and right atrial anchor (RAA) retainer 190'. The component of delivery apparatus 200' which is different from delivery apparatus 200 includes coupler 290' of right atrial anchor (RAA) advancer 270'. As explained below, closure device 100' and delivery apparatus 200' permit adjustments based on the length of the particular PFO tunnel and also permit recapture of closure device 100' by delivery apparatus 200'.

[00104] FIGS. 6A-6B shows anchor connector 150' having three retention holes which are identified at 155a-c. A plurality of retention holes enables retention pawls 199 of right atrial anchor (RAA) retainer 190' to enter holes 155a-c of anchor connector 150' until right atrial anchor 170' is set in a desired position. As the retention pawls 199' are moved in succession in holes 155a-c to bring right atrial anchor 170' closer to left atrial anchor 130, the operator can identify the position of retention pawls 199' with respect to each retention holes 155 by either feeling distinct clicks or by using instrumentation to view their position. The ability to variably set the length of the portion of anchor connector 150' between left atrial anchor 130 and right atrial anchor 170' is advantageous as tunnels 58 have different lengths.

[00105] FIG. 6C provides a detailed depiction of pivot collar 190' which is another example a right atrial anchor (RAA) retainer. Pivot collar 190' has two bands 192' which extend around body portion 196'. Bands 192' each have a ring portion 193' and opposing pivot members 194' at opposite ends of the ring portion 193'. Each pivot member 194' extends through hole 174' and is held in hole 174' by ferrule 195'.

[00106] FIGS. 6D-6G and FIG. 6B show coupler 290' and its torque feature 294'. FIG. 6D shows the portions of pivot members 194'engaged by torque features 294', the portion not in holes 174' of right atrial anchor 170'. As can be seen in FIG. 6G, the space between ring portions 193' of pivot collars 190' and right atrial anchor 170' is filled by coupler 290' when torque features 294' engage pivot members 194'. FIG. 6E shows coupler 290' approaching pivot collar 190'. FIG. 6F shows coupler 290' and pivot collar 190' locked together through the engagement of torque feature 294' and pivot member 194'.

[00107] After the anchors have been deployed on either side of the PFO, the position of the anchors may be observed via fluoroscopic, ultrasonic, or any other type of imaging available to one of skill in the art. If the anchors are in an improper or otherwise undesirable position, they may be recaptured and withdrawn or recaptured and redeployed. In the embodiment depicted in FIGS. 6A-6G, the location of the error in deployment or delivery determines where the recapture occurs. For example, if right atrial anchor 170 has been pushed through tunnel 58 and into left atrium 40 then

catheter 250 is advanced distally through the PFO opening and into the left atrium so that the anchors may then be recaptured in catheter 250. Tip 210 is rotated clockwise enough turns to push retention pawls 199 out of retention holes 155 of anchor connector 150. The operator then pulls on stem 280' of right atrial anchor (RAA) advancer 270' while holding left atrial anchor (LAA) advancer 230. This permits right atrial anchor 170 to be pulled into catheter 250 by utilizing split tip 252 of catheter 250 to pivot right atrial anchor 170 while pulling on stem 280' of right atrial anchor (RAA) advancer 270'. Note that each of retention pawls 199' and holes 155 are shaped to enable retention pawls 199' to remain in place unless lifted by tip 210 for detachment during recapture. More particularly, retention pawls 199 each have a ramp-shaped inner surface and tip 210 lifts retention pawls up so that the ramp-shaped inner surfaces may ride up the edge of holes 155 when right atrial anchor (RAA) advancer 270 is pulled. Catheter 250 recaptures left atrial anchor 130 by pulling left atrial anchor 130 into catheter 250 while split tip 252 is in the left atrium.

[00108] In contrast to having a distinct stem groove 172p and pivot groove 178 like right atrial anchor 170, right atrial anchor 170' has a combined stem and pivot groove 178'. The combined groove 178' is sized to permit easy access by pivot collar 190. Also, once torque feature 294' engages pivot members 194' and the engagement is used to pull right atrial anchor 170' into catheter 250, space is needed within right atrial anchor 170 so that coupler 290' can be received.

[00109] FIGS. 7A-7C depict other embodiments of right atrial anchors respectively at 170a-c. Like right atrial anchors 170 and 170', right atrial anchor 170c has an arched shape. In contrast, right atrial anchors 170a and 170b are relatively straight. Right atrial anchors 170b and 170c have non-resorbable components 162b and 162c and resorbable components 164b and 164c. Examples of resorbable components include components formed from bioresorbable polymers and drug-eluting compositions as described above. A bio-resorbable polymer may be used to give bulk to the anchor and further to promote the formation of fibrous tissue. In such embodiments, the non-resorbable components may be used as a backbone. Although not necessary, a metal wire backbone provides for radio-opacity needed for x-ray imaging. Of course, in some

embodiments the anchors and other components of the closure device may entirely comprise bio-resorbable material such that no foreign material remains in the heart after a sufficient period of time for closure of the PFO to take place. Examples of non-resorbable components include stainless steel and a super-elastic material such as nitinol. These components, like the left atrial anchor, may have any suitable cross-sectional shape. For example, left atrial anchor and the non-resorbable components of the right atrial anchor may be formed from round or flattened wire that has been formed into an appropriate shape or may be wrought from bulk material as desired.

[00110] As shown in FIG. 7A, right atrial anchor 170a has a top surface 175a and a bottom surface 177a which are both relatively straight and parallel to each other. Right atrial anchor 170a has a groove 178a which is open along its entire length except for its center.

[00111] As mentioned above and as shown in FIGS. 7B-7C, right atrial anchors 170b and 170c, respectively have non-resorbable components 162b and 162c and resorbable components 164b and 164c. In these embodiments, the resorbable component and the non-resorbable component are attached to each other. The resorbable components are segmented with notches respectively at 166b and 166c to provide enhanced flexibility. The notches facilitate flexing of the anchor into the arched configuration against the PFO.

[00112] FIGS. 7D-7E depicts another embodiment of a right atrial anchor at 170d. Right atrial anchor 170d has two opposing anchor members joined together by a loops 180 which act as flex points or regions for ends 171 to be flexed together inside a catheter when right atrial anchor 170d is in its delivery configuration. Loops 180 each define a hole 174d. Holes 174d is adapted to engage pivot members 194 or 194' of right atrial anchor (RAA) retainer 190. An optional web 120 is shown extending within the area defined by the wire forming the opposing anchor members. Web 120 may also extend beyond the wire. A hole 184d is provided in web 120 for an anchor connector (not shown in FIGS. 7D-7E) such as anchor connector 150 or 150a.

[00113] FIGS. 8A-8D depict two different embodiments of right atrial anchors which are each positioned adjacent to a septum secundum in anatomical conformance with

the septum secundum. The right atrial anchor is preferably arched with an arch which is similar to that of the septum secundum. Right atrial anchor 170 has an arched top surface 175 which is similar in shape to superior aspect 53, which is the attachment location of septum secundum 54 to septum primum 52. Right atrial anchor also has a length which permits it to be tucked under the overhang of septum secundum 54.

[00114] In addition to being rigid and having an arched configuration, the right atrial anchor can also have other shapes such as a straight configuration while being flexible so that it can conform to the arched shape of the superior aspect 53 of the septum secundum. For example, instead of right atrial anchor 170 being formed from a rigid material, it can also be formed from a more flexible material. Similarly, a flexible embodiment such as shown at 170c may be used.

[00115] FIG. 8B shows right atrial anchor 170 positioned within pocket 59p and the other end positioned on top of anterior portion 57a instead of in pocket 59a. As described above, relying on the anatomy of the posterior portion 57p of septum secundum 54 to position at least one end of right atrial anchor is an effective methodology for effectively closing a PFO. The ends of right atrial anchor are both short enough so that whichever end is positioned in pocket 59p, it conforms with the anatomy of a portion of the septum secundum.

[00116] As shown in FIGS. 8C-8D, a right atrial anchor which is rigid and straight, such as right atrial anchor 170a described above with reference to FIG. 7A, may be used. Right atrial anchor 170a has a posterior end which is short enough to fit within pocket 59p. Although, the rigidity and straight configuration of right atrial anchor 170a prevent it from curving like superior aspect 53, top surface 175a is able to abut superior aspect 53 and septum secundum 54 does not block anchor connector 150 from full access into tunnel 58. The embodiments of the right atrial anchor described above, facilitate closure of the PFO by allowing the right atrial anchor to be tucked under at least a portion of the septum secundum and against the septum primum such that the right atrial anchor can be drawn taughtly against both the septum primum and septum secundum. Healing is thereby facilitated along a greater portion of PFO tunnel 58.

[00117] At the location of a PFO, the septum primum is joined with the septum secundum at two "merger points," as discussed above. The right atrial anchor may be shorter than the distance between these merger points to enhance the ability of the right atrial anchor to be positioned with both of its ends within pockets 59a and 59p. In other words, the right atrial anchor may extend from the point at which the septum primum is joined with the septum secundum on one end of the PFO "arch" to the point at which the septum primum is joined with the septum secundum on the other end of the PFO arch. Contact with these two merger points facilitates the right atrial anchor remaining in its proper position without being pulled through the PFO opening. Because a typical PFO has an arch that is 12-15 mm long, the right atrial anchor typically has a length of about 10 to about 30 mm although variations above and below this are contemplated in order to accommodate varying PFO anatomies. An example of a suitable right atrial anchor has a length within a range of about 15 mm to about 22 mm. An example of a suitable left atrial anchor has a length of about 15 mm to about 30 mm.

[00118] FIG. 9 depicts another embodiment of a left atrial anchor identified at 130' which has three anchor members 132'. Left atrial anchor 130' also has a web material or mesh 120 positioned on anchor members 132' to further facilitate closure of PFO 50. Left atrial anchor may have any suitable number of anchor members. For example, the left atrial anchor may have just two opposing anchor members like the right atrial anchor such that both anchor members are essentially rod-shaped. Similarly, the left atrial anchor may be rod-shaped while the right atrial anchor is banana-shaped. Anchors which are rod-shaped or banana-shaped are referred to herein as elongate-shaped anchors. When both anchors have just two opposing anchor members, the right and left atrial anchors are positioned perpendicular to one another at the point of their approximation such that when they are brought together they generally form a plus (+) shape at that point. With respect to such embodiments, the right atrial anchor is typically placed in an approximately horizontal, although arched, position in the right atrium against and with respect to the PFO and the left atrial anchor is typically placed in an approximately vertical position in the left atrium against the PFO. If not configured in perpendicular orientations with respect to one another, the right and left atrial anchors

will typically at least be offset from one another. In other words, the right atrial anchor will typically be positioned such that it is at an angle with respect to—*i.e., not* parallel to—the left atrial anchor such that are positioned in intersecting planes with respect to one another. Also, one or both anchors may have an off-center pivot point.

[00119] FIG. 10 depicts another embodiment of a closure device at 100". Closure device 100" has a right atrial anchor 170" comprising a single wire looped to have opposing anchor members. Right atrial anchor 170" is connected to left atrial anchor 130" via an anchor connector 150" which is a ring with either an elliptical or round shape. From the view of FIG. 10, only two anchor members of left atrial anchor 130" are depicted. However, as understood from the juncture of the anchor members, left atrial anchor 130", in this embodiment, has four anchor members.

[00120] FIG. 11 depicts another closure device at 100'". Closure device 100'" is formed from an integral material. Closure device 100'" has an anchor connector 150'" which is integral at one end with a left atrial anchor 130'" and is integral at the other end with right atrial anchor 170'". Anchor connector 150'" is coated with a coating which facilitates closure of PFO 50. Examples of suitable coatings include bioresorbable polymers and drug-eluting compositions. Closure device 100'" is shaped to enable conformance with the anatomy of septum primum 52, septum secundum 54 and tunnel 58.

[00121] FIGS. 12A-12C depict another embodiment of a closure device 100a comprising a left atrial anchor 130a and a right atrial anchor 170" which are connected together by an anchor connector 150a. FIGS. 12A-12C also depict 200" another embodiment of delivery apparatus 200 having a left atrial anchor (LAA) advancer 230" and a right atrial anchor (LAA) advancer 270". Left atrial anchor 130a has a first set of anchor members 132a on top of a second set of anchor members 132a. The two sets are identical. The tips 134a of anchor members 132a are joined together at joints 135a. FIG. 13A provides a plan view of left atrial anchor 130a and FIG. 14A provides an enlarged cross-sectional view of joint 135a.

[00122] Left atrial anchor (LAA) advancer 230" pushes left atrial anchor 130a out of catheter 250 and into the left atrium. FIG. 12B provides a perspective view of left atrial

anchor 130a during deployment. Anchor connector 150a of closure device 100a is a thread or filament. Anchor connector 150a is tied to first center feature 138a of left atrial anchor 130a at end 153a. Anchor connector 150a has a stop 152a which is passed over by second center feature 139a of the second set of anchor members 132a as second center feature 139a is pushed towards first center feature 138a. Anchor connector 150a can be used to selectively expand or collapse left atrial anchor 130a.

[00123] FIG. 12C provides a perspective view of left atrial anchor 130a as compressed in a left atrium and right atrial anchor 170" as positioned in the right atrium by right atrial anchor (LAA) advancer 270". Right atrial anchor 170" has an opening 184 through which anchor connector 150a passes. Right atrial anchor 170" also has a right atrial anchor (RAA) retainer 190" also referred to as a locking arm. Locking arm 190" permits right atrial anchor 170" to advance on anchor connector 150a toward left atrial anchor 130a. While other embodiments permit right atrial anchor 170" to be retracted on anchor connector, locking arm 190" does not permit right atrial anchor 170" to be moved away from left atrial anchor 130a. Note that coupler 290" of right atrial anchor (LAA) advancer 270" has a torque feature 294" for engaging torque groove 168 of right atrial anchor 170".

[00124] Other configurations of left atrial anchor 130a having two sets of linked anchor members are shown in FIGS. 13B-13D and are identified as 130b-130d. FIGS. 14B-C provide enlarged cross-sectional views of joints 135b-c. FIG. 14D is a side view of left atrial anchor 130d being pulled slightly at its center.

[00125] FIGS. 13E-13F depict additional embodiments of left atrial anchors as identified at 130e-130f. Left atrial anchor 130e depicts an embodiment having six anchor members 132e.

[00126] FIG. 15A and FIG. 15B depict embodiments of webs respectively at 122 and 122'. Another embodiment of a web, web 122f is shown in FIG. 13F and FIG. 15C as used in combination with left atrial anchor 130e to provide left atrial anchor 130f. Web 122f comprises arm links 123f, a perimeter link 124f and an inset link 125f. Perimeter link 124f comprises link components which are either integral or separate and are attached to each end or tip 134 of each anchor member 132e. Arm links 123f and inset

link 125f may also comprise link components which are either integral or separate. Web 122 shown in FIG. 15A differs from web 122f in that it does not have an inset link. Web 122' shown in FIG. 15B differs from web 122f as web 122' has a plurality of inset links. The inset links extending around a perimeter at certain lengths of each anchor member.

[00127] FIG. 15C depicts a plan view of left atrial anchor 130f shown in FIG. 13F with anchor connector 150f in the center of anchor 130f. The combination of webbed links on anchor members as shown in FIG. 13F permits left atrial anchors 130f to have a triangulated configuration as shown in FIG. 15C. The links may be flexible and have some tensile strength but limited compressive strength much like a string. When flexible links are used in combination with arms which are relatively rigid, the combination permits compression within a catheter in a delivery configuration and a deployed configuration which resists collapsing and being pulled into tunnel 58.

[00128] Triangulation anchors such as anchor 130f may have various configurations. For example, the links do not need to by symmetrical, integral or linked continuously on the anchor members. The webs may be formed from the same or different materials as the anchor members. For example, the anchor members may be formed from nitinol while the links are formed from resorbable polymers. Webs 122 and mesh 120 shown with reference to FIG. 9 and FIG. 7D may be used with either a left atrial anchor or a right atrial anchor. Materials may also be used as a mesh or links which have a fuzzy appearance. Triangulation atrial anchors are not shown with a web material, however, it should be understood that such an embodiment acts much like an umbrella.

[00129] Since the embodiments disclosed herein have right and left atrial anchors that are coupled to one another—i.e., they are integral, attached, or otherwise connected with one another—once the anchors have each been deployed, they will remain in place on either side of the PFO opening.

[00130] Right atrial anchor and left atrial anchor can be coupled together by any available structure or in any available manner. For example, the respective anchors may be considered "coupled" if they are integral, attached, or otherwise connected with one another. The atrial anchor may be shaped to provide a torsion-spring-like flexural pivot that minimizes strain in the anchor material as it is deformed between the delivery

configuration and the deployed configuration and vice versa. Note that while anchor connectors 150, 150' and 150a are shown as the structure for coupling the right and left atrial anchors, some embodiments of the invention don't have a connector at all. For example, portions of the anchors may extend into or through tunnel 58 to join the anchors together. Also, the anchors could be welded, glued, or integrally connected. Moreover, a variety of other suitable structures or other arrangements could be used to connect the anchors, such as a cable, filament, chain, clip, clamp, band, or any other manner of connection available to those of skill in the art.

[00131] All publications, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference as if each individual publication were specifically and individually indicated to be incorporated by reference herein as though fully set forth.

[00132] The above description fully discloses the invention including preferred embodiments thereof. Without further elaboration, it is believed that one skilled in the art can use the preceding description to utilize the invention to its fullest extent.

[00133] It will be apparent to those having skill in the art that changes may be made to the details of the above-described embodiments without departing from the underlying principles of the invention. Embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows.

Claims

1. A method for facilitating closure of a patent foramen ovale (PFO), comprising the steps of:

obtaining a closure device comprising a left atrial anchor coupled with a right atrial anchor;

deploying the left atrial anchor of the device in the left atrium of a heart and positioning the left atrial anchor proximate to the PFO such that one end of the left atrial anchor is positioned against the septum primum of the heart and the other end of the left atrial anchor is positioned against the septum secundum of the heart; and

deploying the right atrial anchor in the right atrium of the heart and positioning the right atrial anchor proximate to the opposite side of the PFO such that at least a portion of the right atrial anchor is tucked under the septum secundum and against the septum primum in conformance with the anatomy of the PFO to enable the left atrial anchor and right atrial anchor to be respectively held in the left atrium and the right atrium against the septum primum and septum secundum.

2. The method of claim 1, wherein the closure device further comprises an anchor connector, wherein the anchor connector is connected to the left atrial anchor at one end and connected to the right atrial anchor at the other end such that the angle of the right atrial anchor in the right atrium relative to the anchor connector and the angle

of the left atrium anchor in the left atrium relative to the anchor connector permit the anchor connector to conform to the anatomy of the tunnel of the PFO.

3. The method of claim 1, wherein the closure device further comprises an anchor connector, wherein the anchor connector is connected to the left atrial anchor in a configuration which permits the left atrial anchor to pivot in any plane, and wherein the anchor connector is connected to the right atrial anchor in a configuration which permits the right atrial anchor to pivot in only one plane.

4. The method of claim 1, wherein the right atrial anchor is flexible.

5. The method of claim 1, wherein the right atrial anchor is arched.

6. The method of claim 1, wherein the right atrial anchor has a contact surface which is relatively straight.

7. The method of claim 1, wherein the right atrial anchor is integral.

8. The method of claim 1, wherein the right atrial anchor has two opposing anchor members joined together at a flexible region.

9. The method of claim 1, wherein at least one of the right atrial anchor and the left atrial anchor is coated with at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

10. The method of claim 1, wherein at least one of the right atrial anchor and the left atrial anchor comprises at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

11. The method of claim 1, wherein the left atrial anchor comprises at least three anchor members.

12. The method of claim 1, wherein deploying the right atrial anchor involves rotating the right atrial anchor clockwise until one of its ends is tucked under a portion of the septum secundum.

13. The method of claim 1, wherein the right atrial anchor has two opposing anchor members and an axis extending through the anchor members and wherein the axis of the deployed right atrial anchor intersects the plane of the left atrial anchor as deployed against the heart.

14. A method for facilitating closure of a patent foramen ovale (PFO), comprising the steps of:

obtaining a device comprising a left atrial anchor coupled with a right atrial anchor, wherein the right atrial anchor has only two opposing anchor members;

deploying the left atrial anchor of the device in the left atrium of a heart and positioning the left atrial anchor proximate to the PFO such that such that a portion of the left atrial anchor is positioned against the septum primum of the heart and another such that a portion of the left atrial anchor is positioned against the septum secundum of the heart; and

deploying the right atrial anchor in the right atrium of the heart and positioning the right atrial anchor proximate to the opposite side of the PFO such that at least a portion of the right atrial anchor conforms with the anatomy of the PFO in an arched configuration with at least a portion of the right atrial anchor tucked under the septum secundum and against the septum primum such that the left atrial anchor and right atrial anchor are respectively held in the left atrium and the right atrium against the septum primum and septum secundum.

15. The method of claim 14, wherein deploying the right atrial anchor enables the right atrial anchor to extend at least as long as a portion of the arch in the inferior aspect of the septum secundum between the merger points of the PFO.

16. A method for facilitating closure of a patent foramen ovale (PFO), comprising the steps of:

introducing a catheter containing a device comprising a left atrial anchor coupled with a right atrial anchor through the PFO and into the left atrium of a patient's heart;

deploying the left atrial anchor in the left atrium from the catheter;

positioning the left atrial anchor proximate to the PFO such that a portion of the left atrial anchor is positioned against the septum primum of the heart and another portion of the left atrial anchor is positioned against the septum secundum of the heart;

deploying the right atrial anchor in the right atrium of the heart from the catheter; and

positioning the right atrial anchor proximate to the opposite side of the PFO such at least a portion of the right atrial anchor generally follows the arch formed by the inferior aspect of the septum secundum along the periphery of the PFO.

17. The method of claim 16, wherein the right atrial anchor has at least one end extending toward one of the merger points at which the septum secundum and septum primum come together at the edges of the PFO.

18. The method of claim 16, further comprising the step of recapturing the right and left atrial anchors in the catheter.

19. A device for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to be positioned at the PFO in the left atrium of the heart in a deployed configuration; and

a right atrial anchor,

wherein the right atrial anchor is adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the right atrium of the heart in a deployed configuration,

wherein the right atrial anchor has only two opposing anchor members; and

wherein the right atrial anchor has a length and shape which permit at least a portion of the right atrial anchor to be tucked under the septum secundum and against the septum primum in conformance with the anatomy of the PFO; and

an anchor connector, wherein the anchor connector is connected to the left atrial anchor at one end and connected to the right atrial anchor at the other end such that the angle of the right atrial anchor in the right atrium relative to the anchor connector and the angle of the left atrium anchor in the left atrium relative to the anchor connector permit the anchor connector to conform to the anatomy of the tunnel.

20. The device of claim 19, wherein the right atrial anchor is rigid.

21. The device of claim 19, wherein the right atrial anchor is flexible.

22. The device of claim 19, wherein the right atrial anchor is arched.

23. The device of claim 19, wherein the right atrial anchor has a contact surface which is relatively straight.

24. The device of claim 19, wherein the right atrial anchor is integral.

25. The device of claim 19, wherein the two opposing anchor members of the right atrial anchor are joined together at a flexible region.

26. The device of claim 19, wherein at least one of the right atrial anchor and the left atrial anchor is coated with at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

27. The device of claim 19, wherein at least one of the right atrial anchor and the left atrial anchor comprises at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

28. The device of claim 19, wherein the left atrial anchor comprises at least three anchor members.

29. The device of claim 19, wherein the left atrial anchor comprises a plurality of anchor members and at least one anchor member is in a different plane relative to another anchor member.

30. A device for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to be positioned at the PFO in the left atrium of the heart in a deployed configuration,

wherein the left atrial anchor is adapted to pivot in any plane; and

a right atrial anchor coupled with the left atrial anchor, wherein the right atrial anchor is adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the right atrium of the heart in a deployed configuration,

wherein the right atrial anchor has two opposing anchor members, and

wherein the right atrial anchor is adapted to pivot in only one plane.

31. A device for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to be positioned at the PFO in the left atrium of the heart; and

a right atrial anchor coupled with the left atrial anchor, wherein the right atrial anchor is adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the right atrium of the heart in a deployed configuration,

wherein the right atrial anchor has two opposing anchor members, and,

wherein the right atrial anchor has a length and shape which permit at least a portion of the right atrial anchor to be tucked under the septum secundum and against the septum primum in conformance with the anatomy of the PFO.

32. A device for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the left atrium of the heart in a deployed configuration; and

a right atrial anchor, wherein the right atrial anchor is adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the right atrium of the heart in a deployed configuration, wherein the right atrial anchor has two opposing anchor members; and

an anchor connector, wherein the anchor connector is connected to the left atrial anchor in a configuration which permits the left atrial anchor to pivot in any plane, and wherein the anchor connector is connected to the right atrial anchor in a configuration which permits the right atrial anchor to pivot in only one plane.

33. The device of claim 32, wherein at least one of the right atrial anchor, the left atrial anchor and the anchor connector is coated with at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

34. The device of claim 32, wherein at least one of the right atrial anchor, the left atrial anchor and the anchor connector comprises at least one of a bioresorbable

polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

35. A device for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the left atrium of the heart in a deployed configuration, the left atrial anchor comprising a plurality of anchor members radially extending from a center and a web, wherein the web has link components which link the anchor members in a manner which permits the anchor members to pivot in a limited angle between the delivery configuration to the deployed configuration while preventing further pivoting beyond the deployed configuration; and

a right atrial anchor coupled with the left atrial anchor.

36. The device of claim 35, wherein the anchor members have ends and the link components are attached to each end of each anchor member to form a perimeter link.

37. The device of claim 35, further comprising an anchor connector, wherein the anchor connector is connected to the left atrial anchor and the right atrial anchor.

38. A device for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to be positioned at the PFO in the left atrium of the heart; and

a right atrial anchor adapted to be positioned at the PFO in the right atrium of the heart;

an anchor connector, wherein the anchor connector is integrally connected to the left atrial anchor and integrally connected to the right atrial anchor; and

a coating on at least a portion of the anchor connector which facilitates closure of a patent foramen ovale.

39. The device of claim 38, wherein the coating is at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

40. The device of claim 38, wherein at least one of the right atrial anchor, the left atrial anchor and the anchor connector comprises at least one of a bioresorbable polymer, a drug eluting composition, a protein, a growth factor and a combination thereof.

41. An apparatus for facilitating closure of a patent foramen ovale (PFO), comprising:

a left atrial anchor adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the left atrium of the heart in a deployed configuration; and

a right atrial anchor coupled with the left atrial anchor that is adapted to fit within a catheter in a delivery configuration and adapted to be positioned at the PFO in the right atrium of the heart in a deployed configuration, wherein the right atrial anchor is shaped and adapted to be placed along the arch formed by the inferior aspect of the septum secundum along the periphery of the PFO in the right atrium of the heart, wherein the right atrial anchor has a length which enables the right atrial anchor to extend along the arch between the merger points at which the septum secundum and septum primum come together at the edges of the PFO.

42. A system for facilitating closure of a patent foramen ovale (PFO), comprising:

a device comprising:

a left atrial anchor adapted to be fit within the catheter and to be positioned at the PFO in the left atrium of the heart in a deployed configuration; and

a right atrial anchor coupled with the left atrial anchor that is adapted to fit within a catheter in a delivery configuration and adapted to

be positioned at the PFO in the right atrium of the heart in a deployed configuration, wherein the right atrial anchor is shaped and sized to permit at least a portion of the right atrial anchor along the arch formed by the inferior aspect of the septum secundum along the periphery of the PFO in the right atrium of the heart;

and a delivery apparatus comprising:

a catheter,

means for controlling the position of the left atrial anchor; and

means for controlling the position of the right atrial anchor.

43. The system of claim 42, wherein the means for controlling the position of the left atrial anchor and the means for controlling the position of the right atrial anchor also serve to allow the device to be recaptured in the catheter.

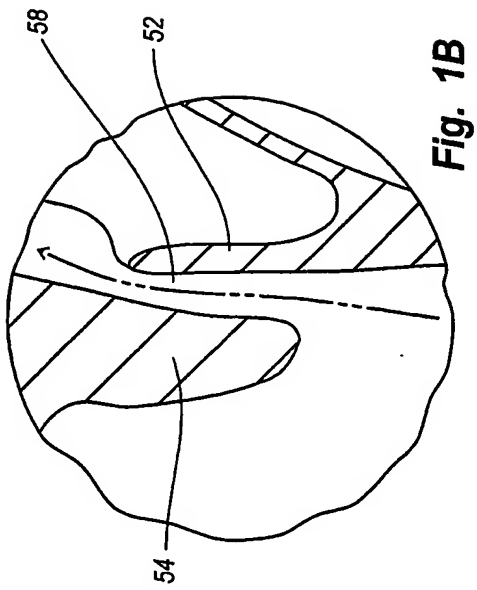

Fig. 1B

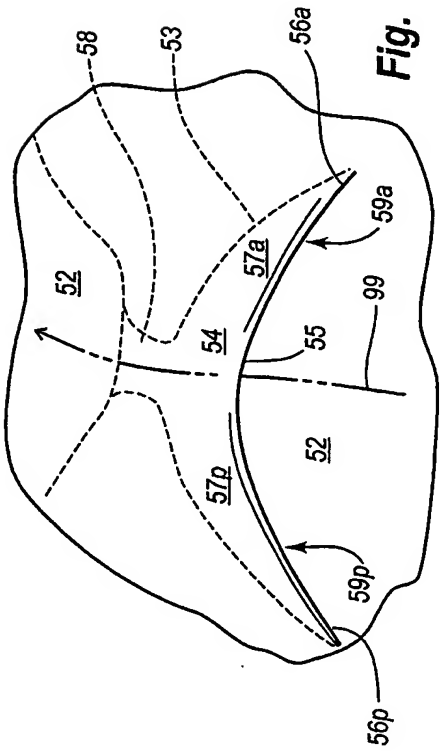

Fig. 1C

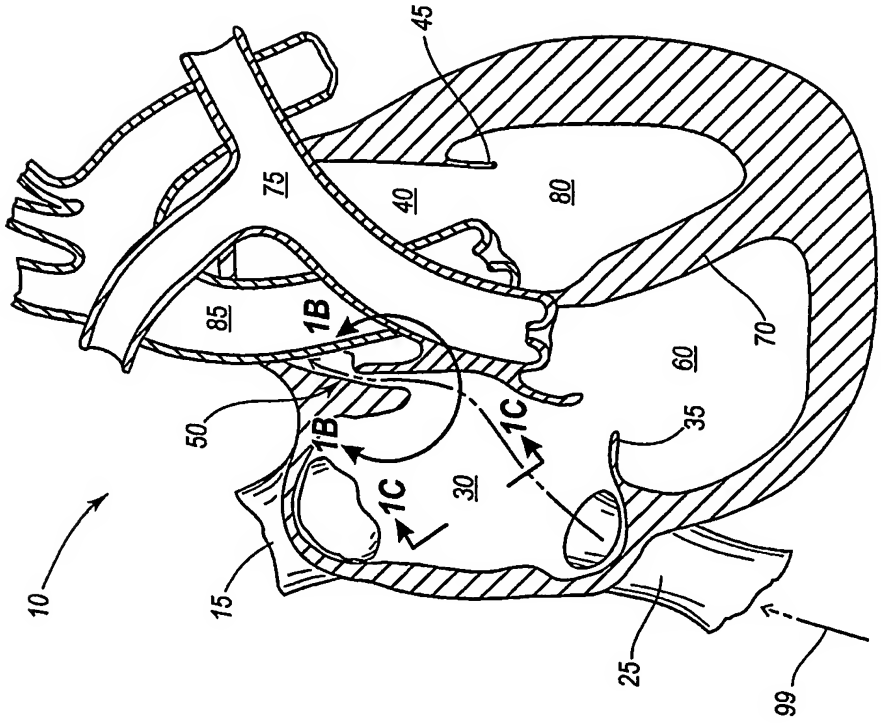

Fig. 1A

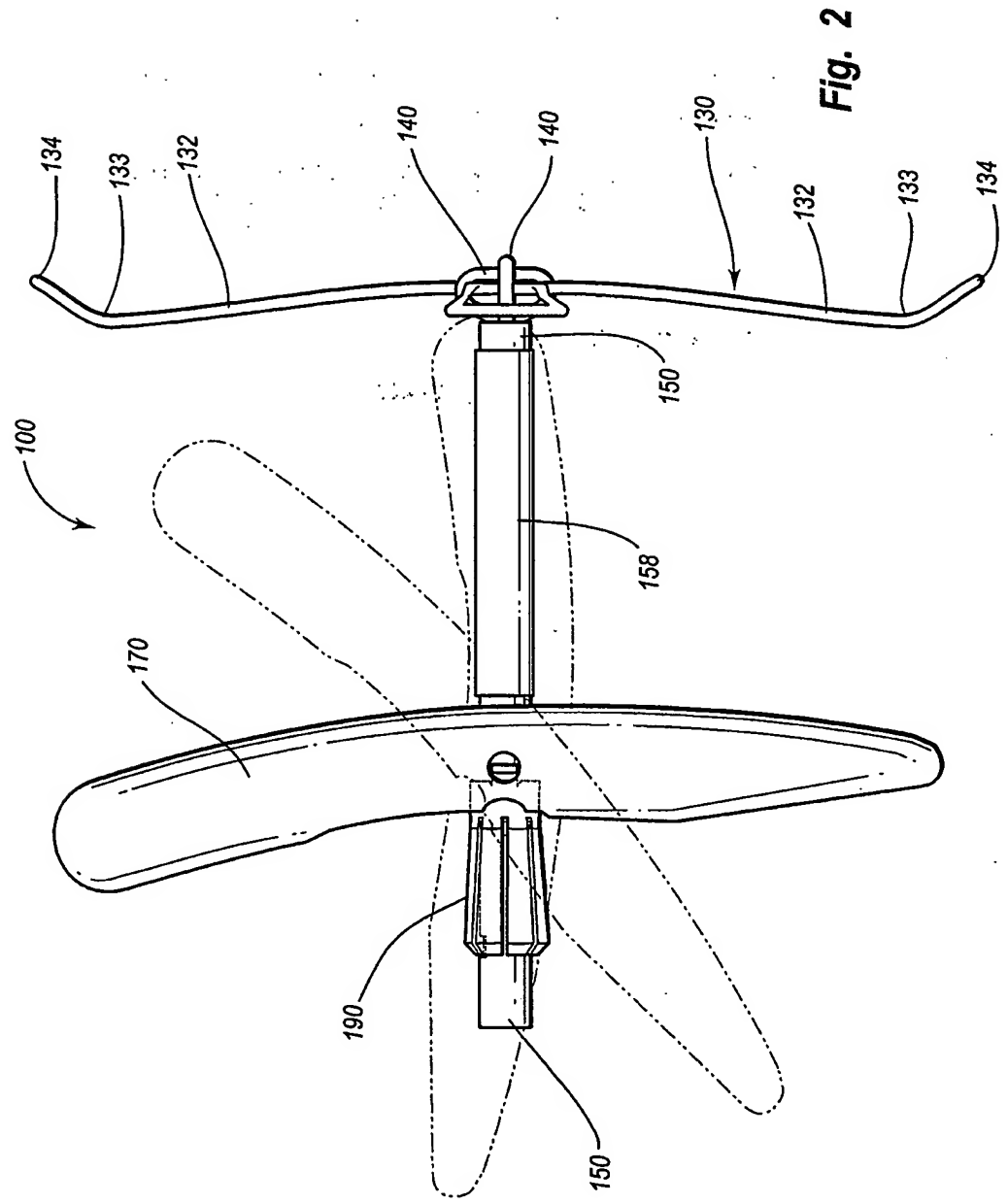

Fig. 2

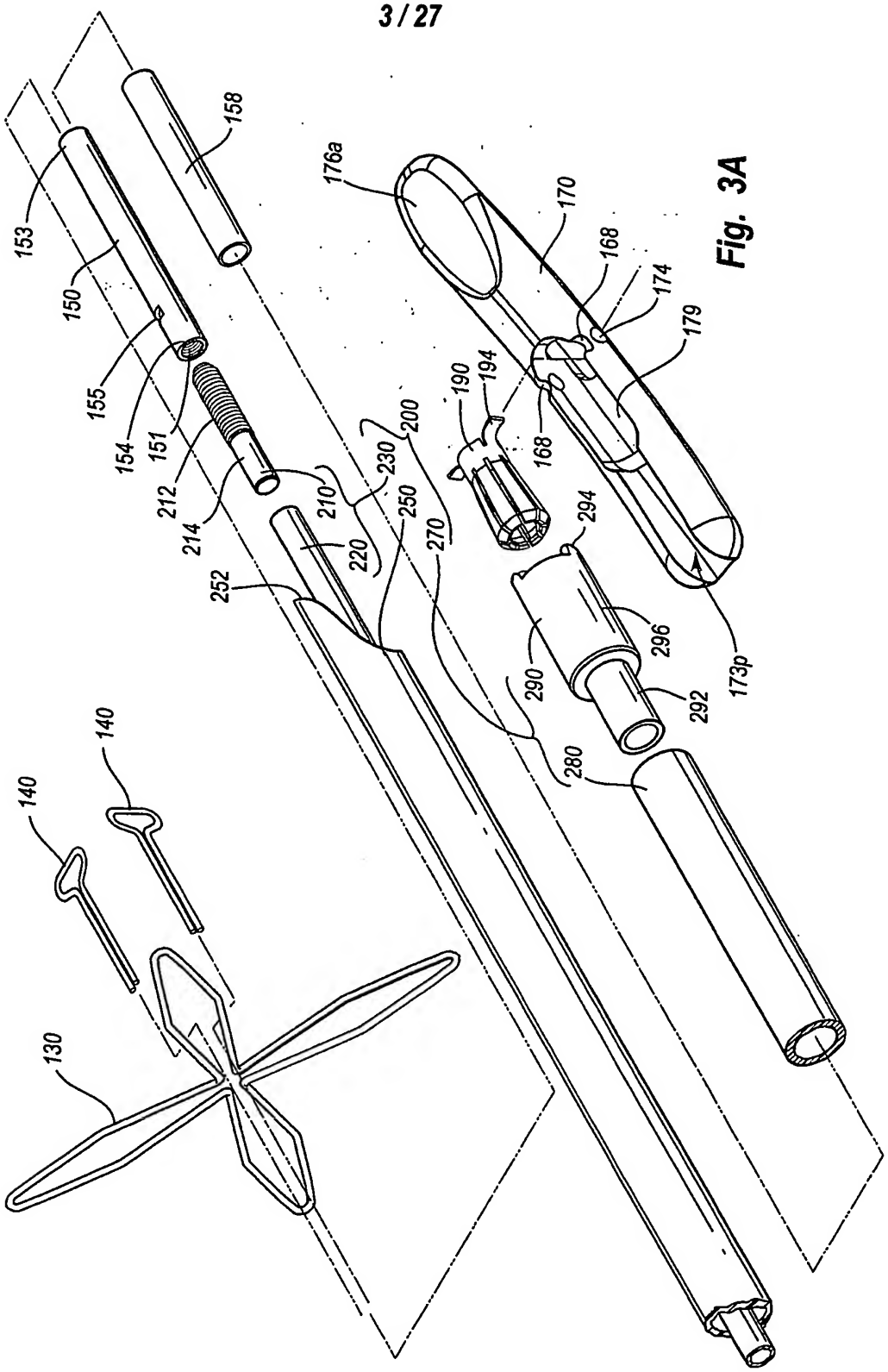
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Fig. 3A

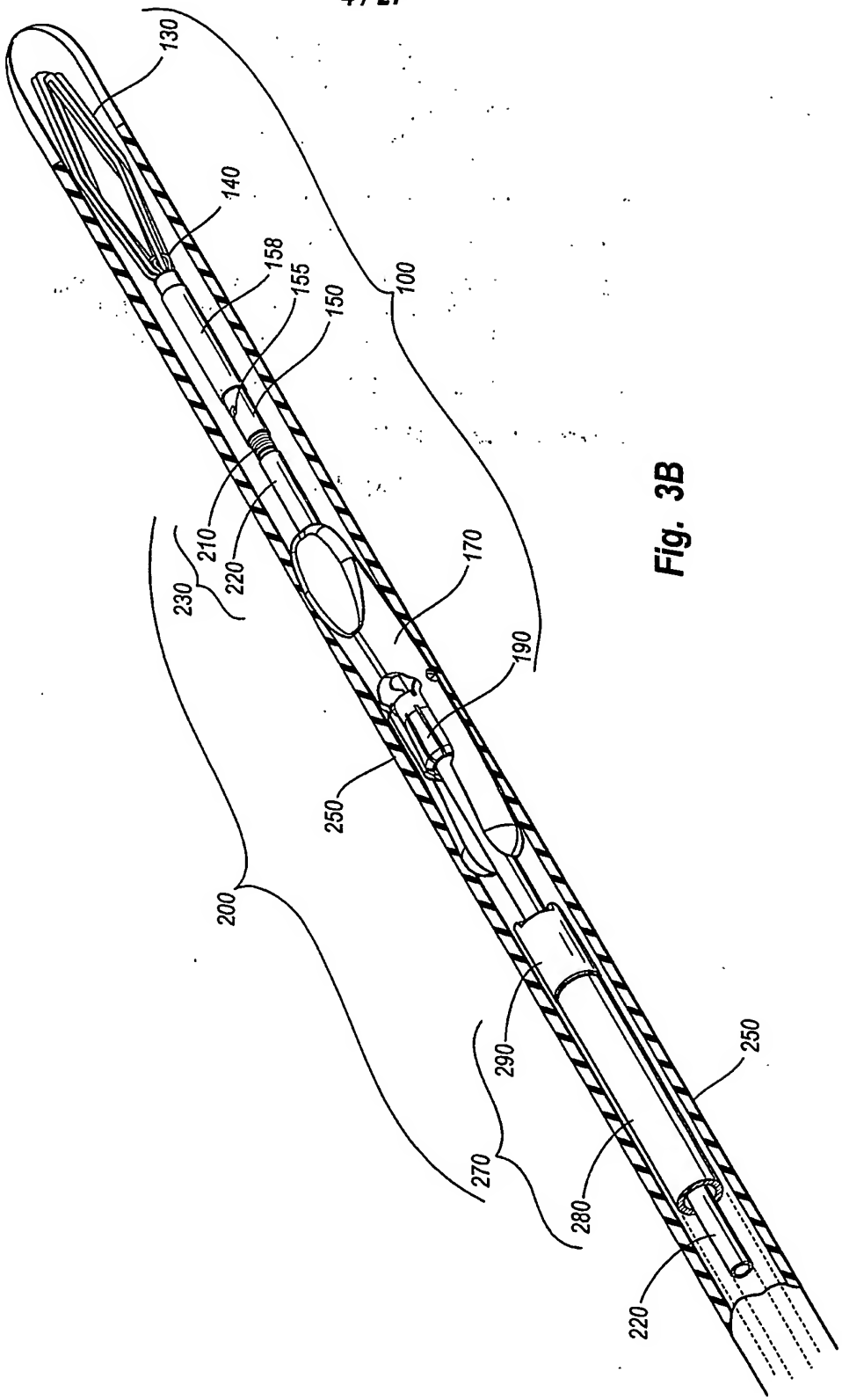
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Fig. 3B

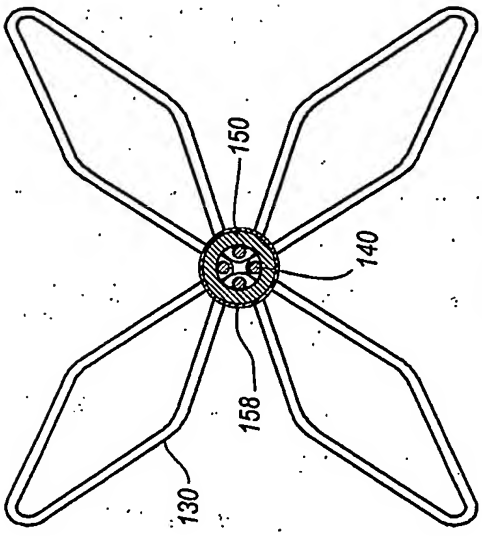
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Fig. 4B

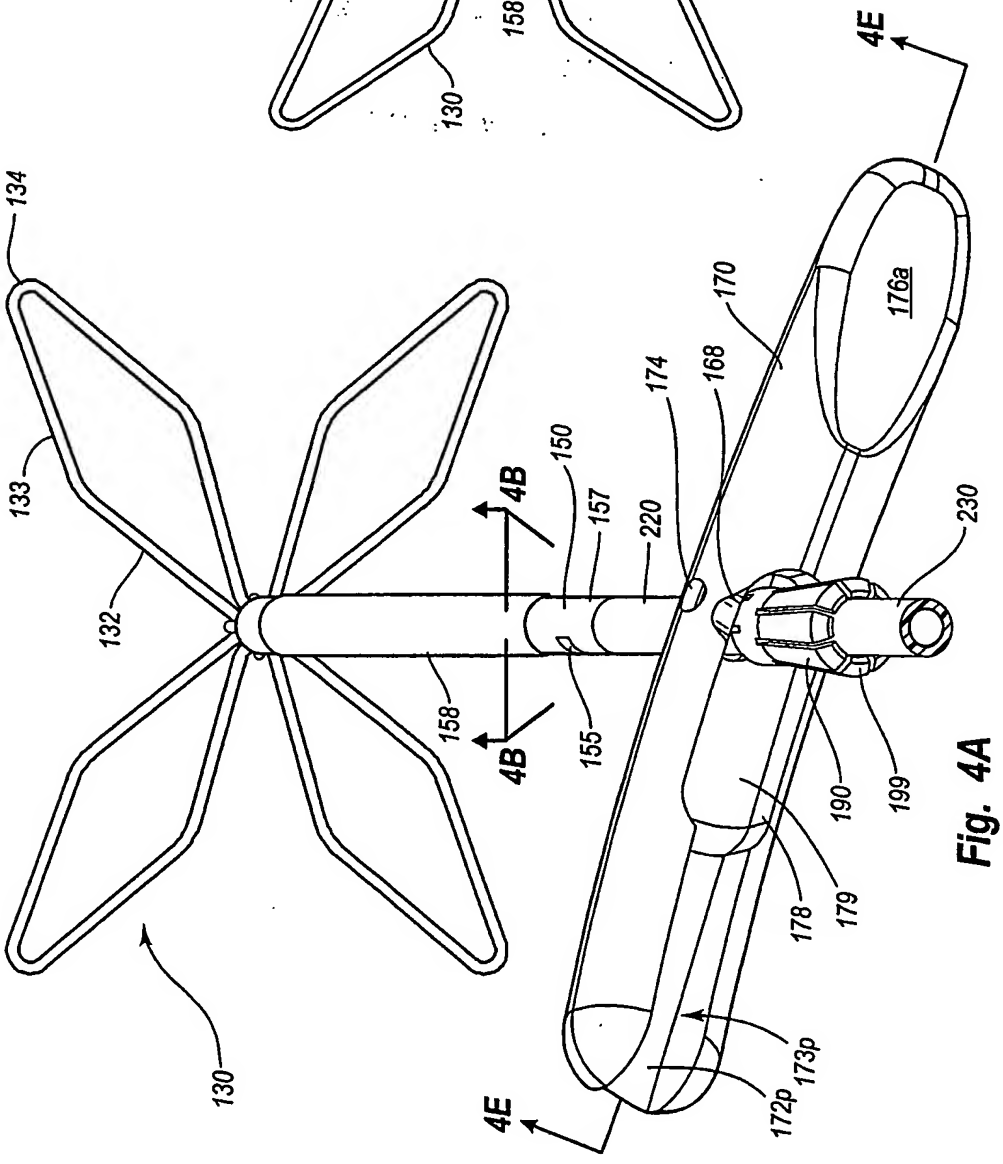
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Fig. 4A

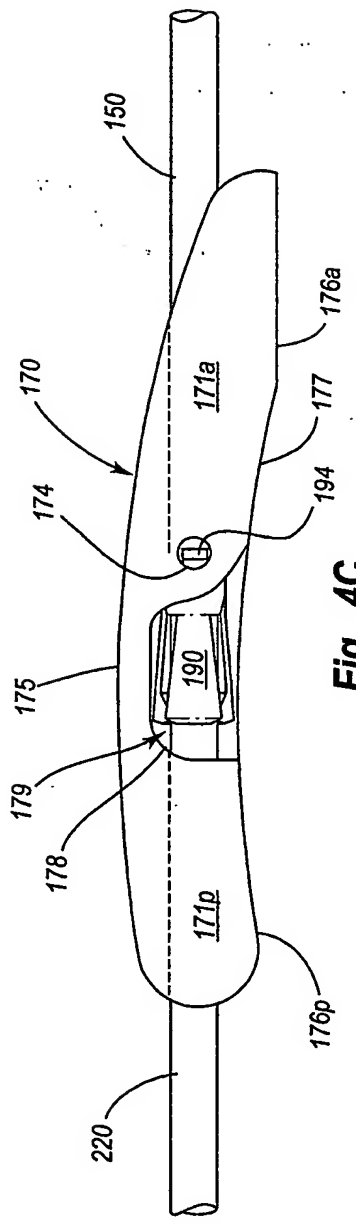
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Fig. 4C

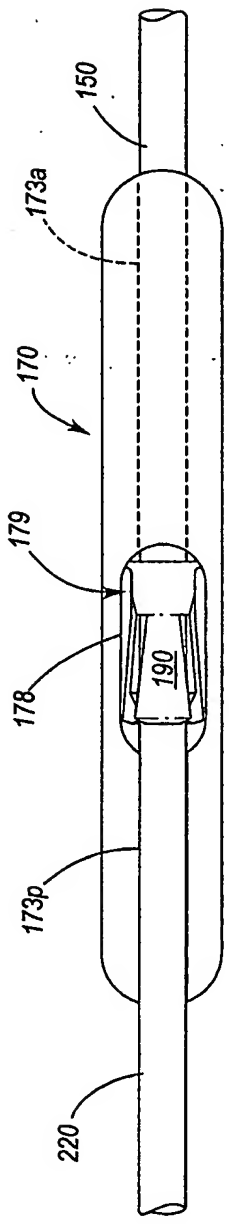
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Fig. 4D

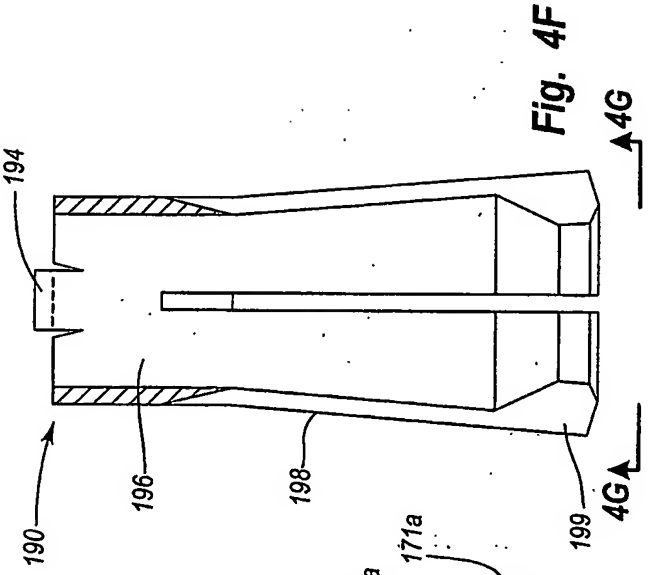


Fig. 4F

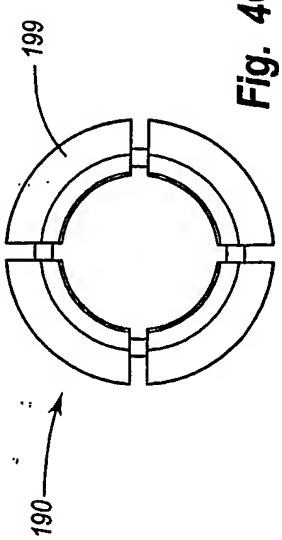
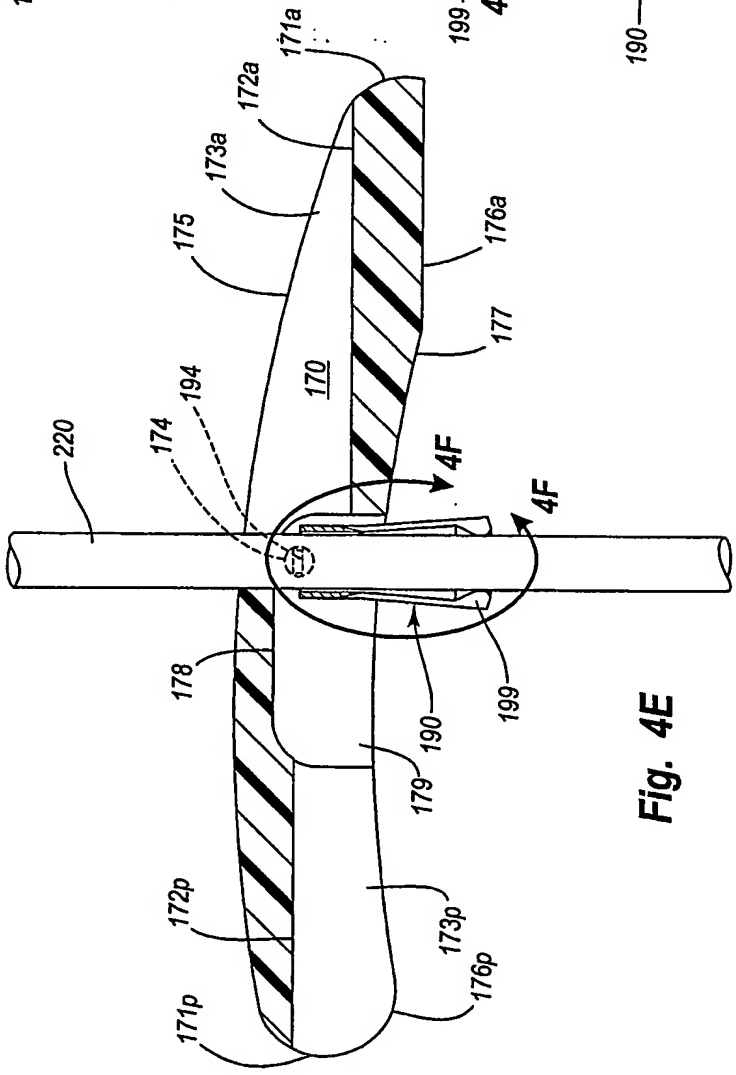


Fig. 4G



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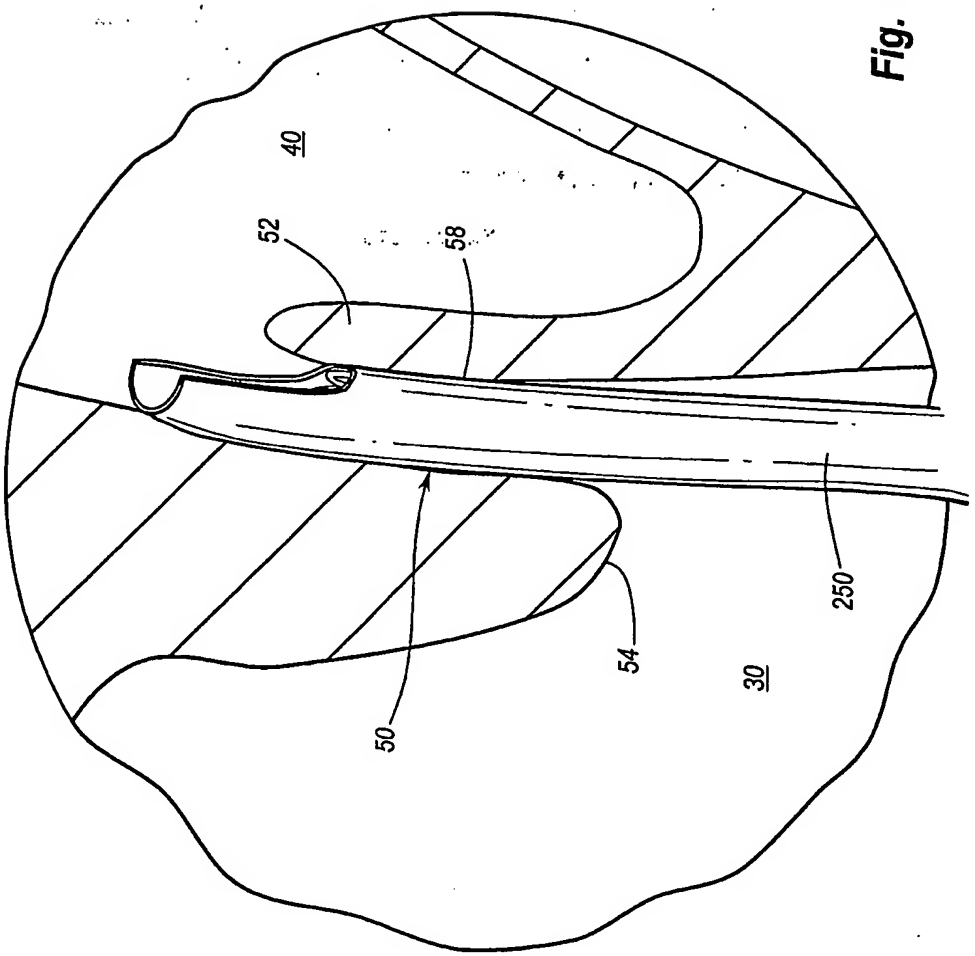

Fig. 5A

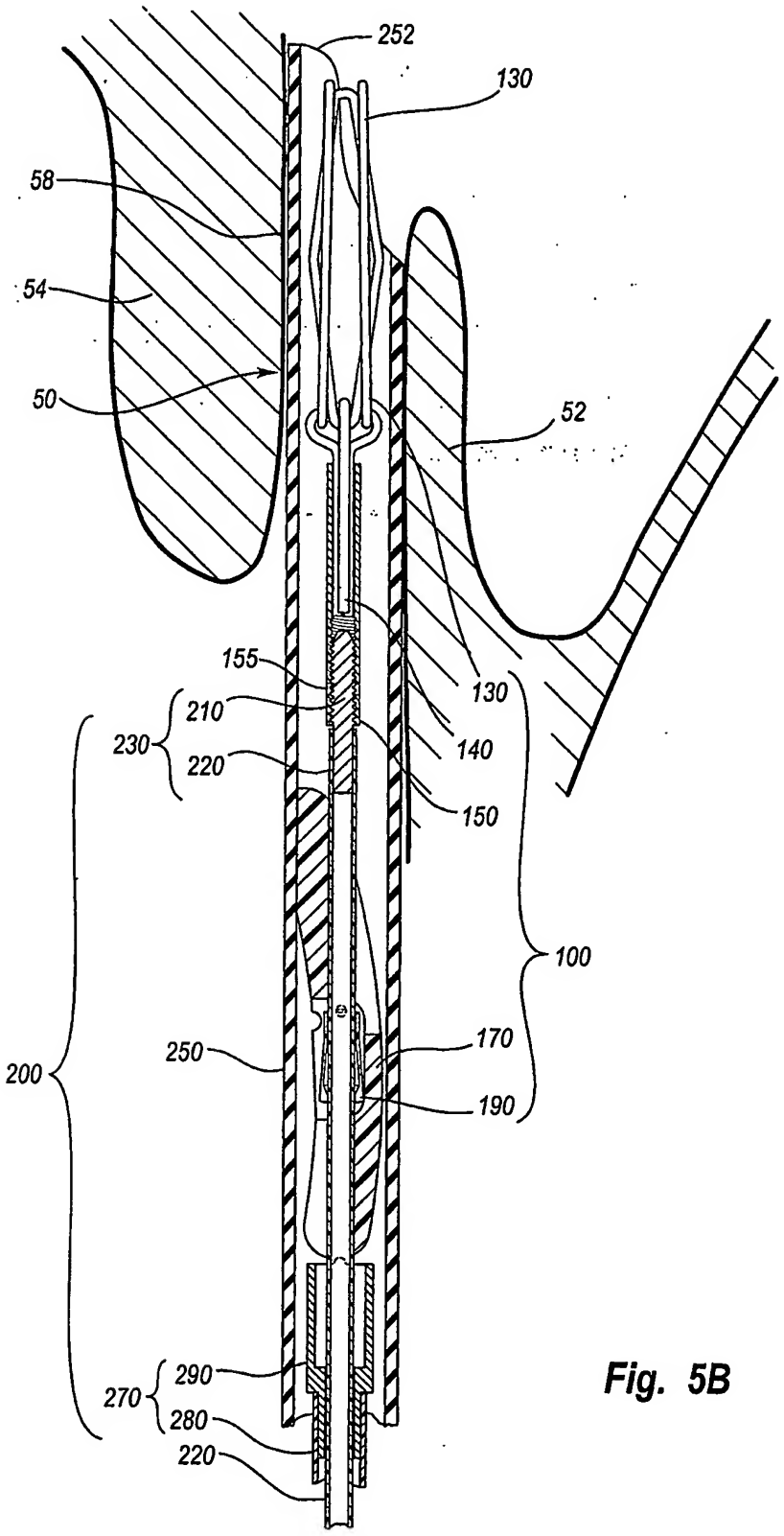
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Fig. 5B

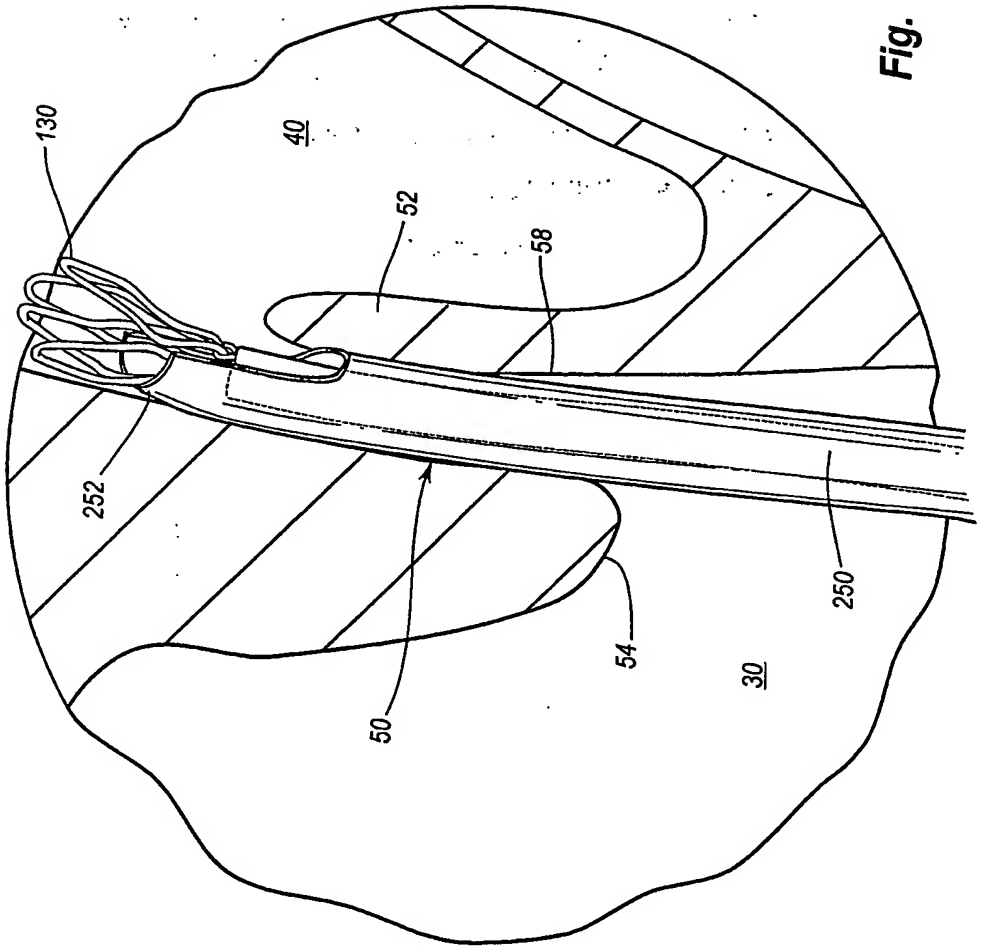

Fig. 5C

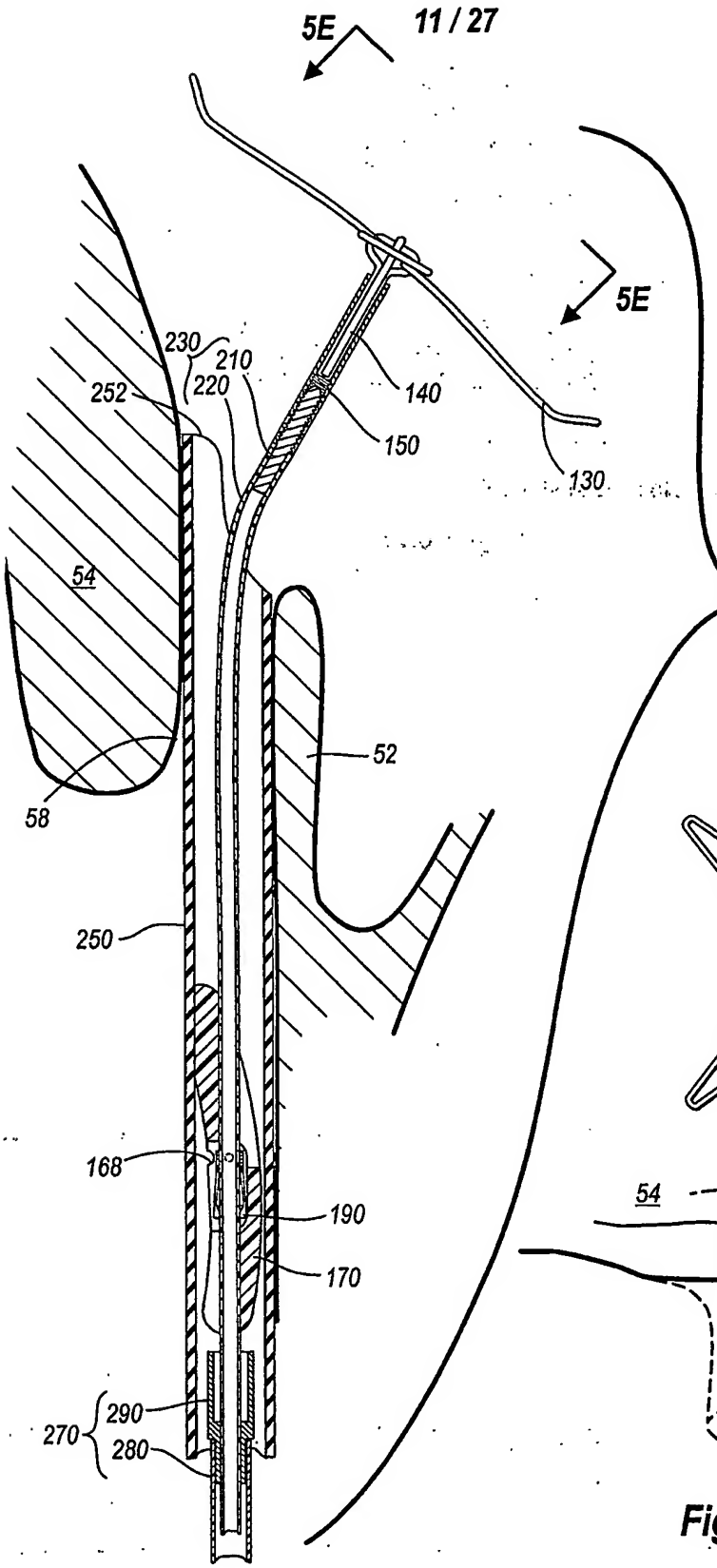
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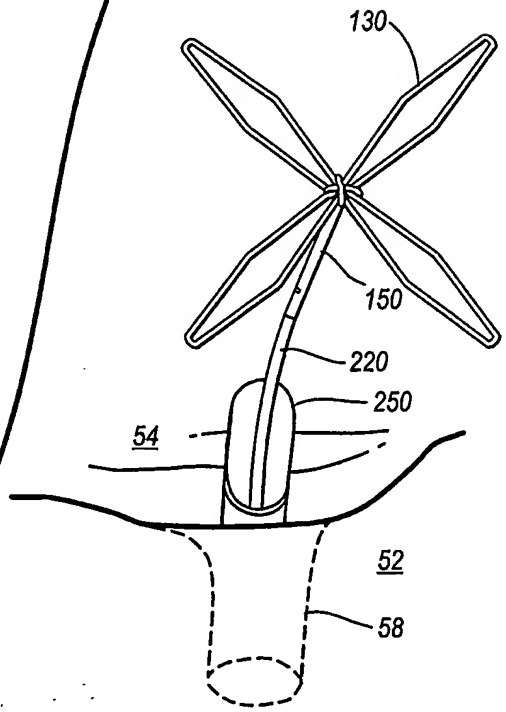
Fig. 5D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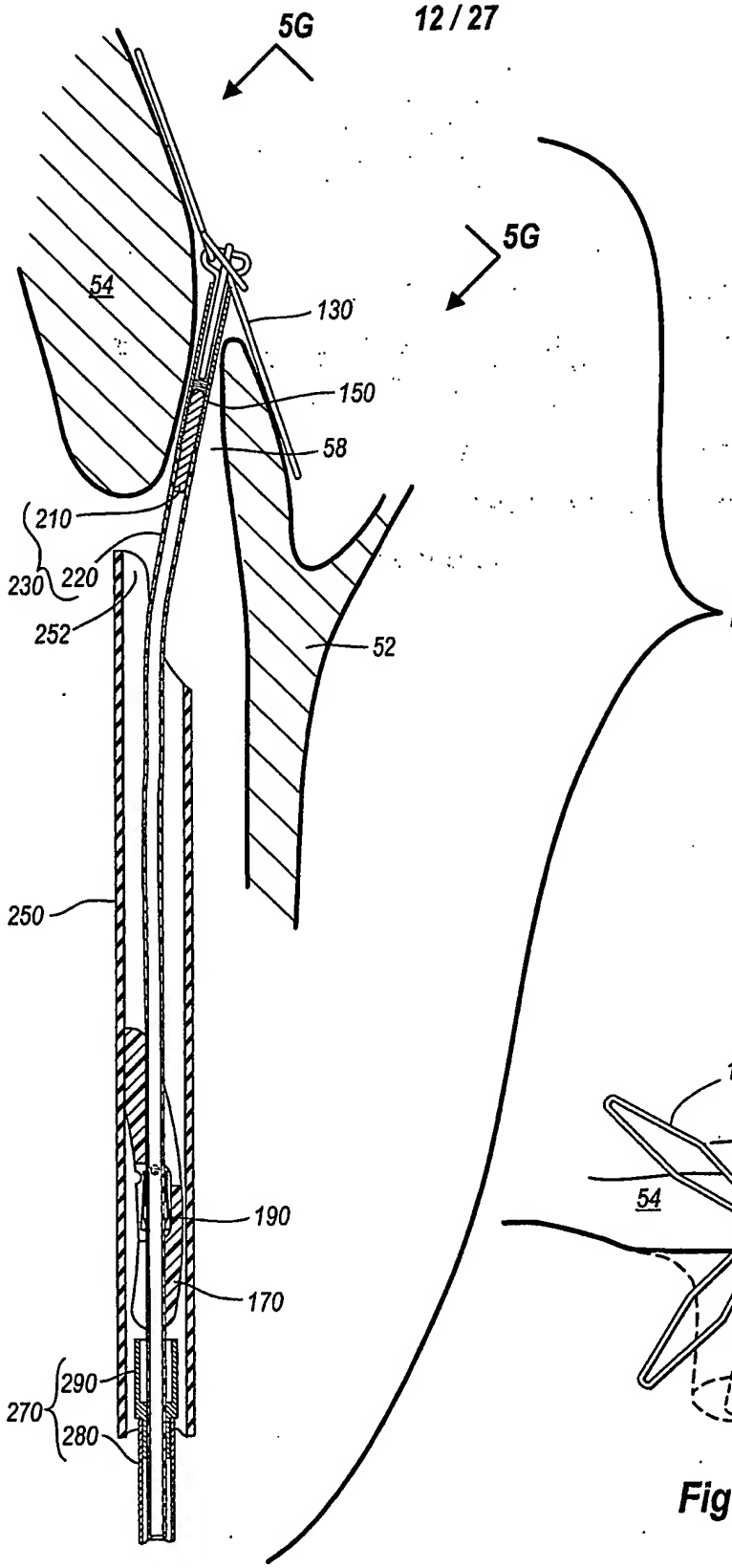
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Fig. 5F

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Fig. 5G

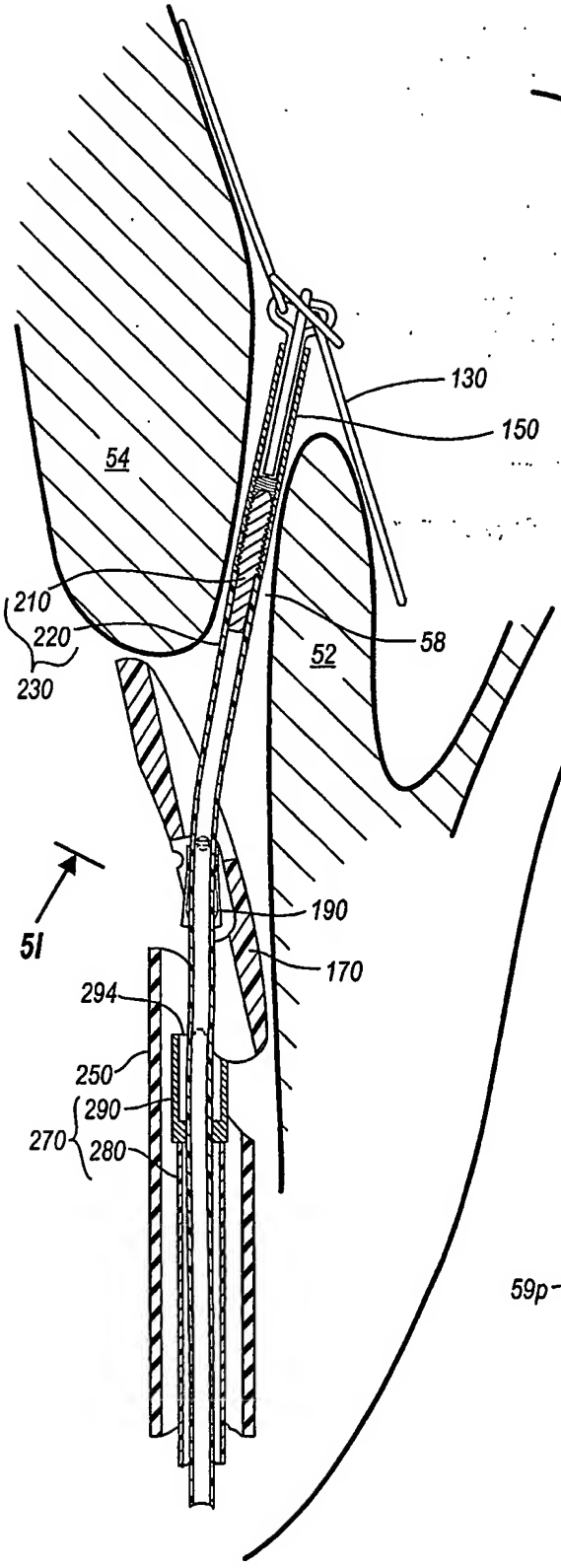
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Fig. 5H

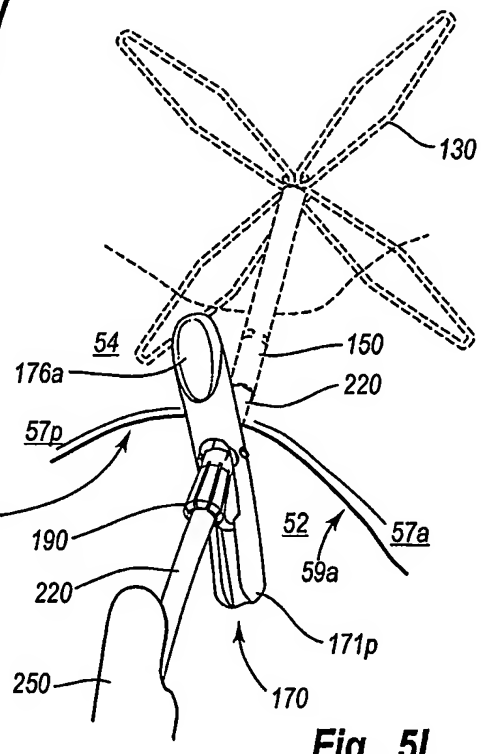
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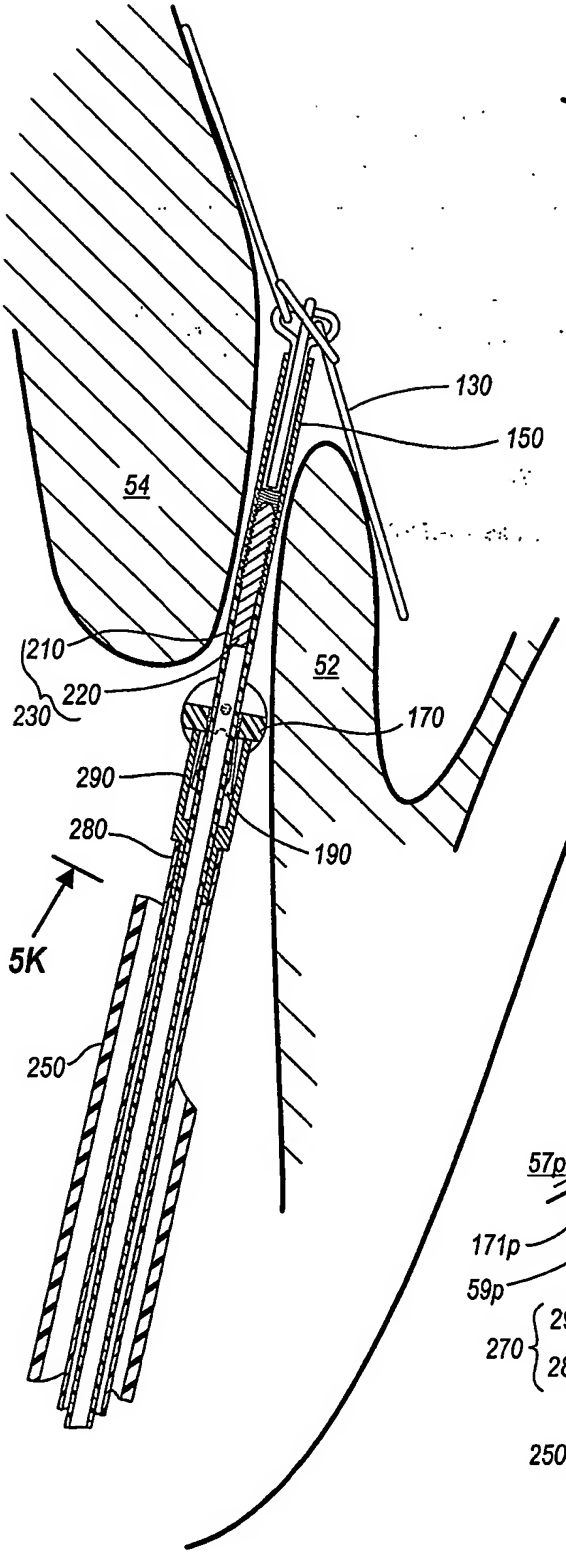
Fig. 5I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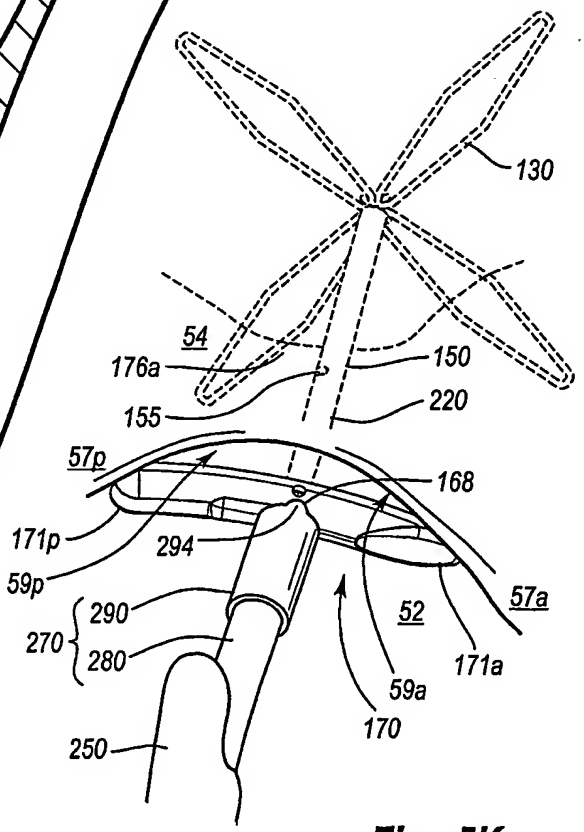
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Fig. 5K

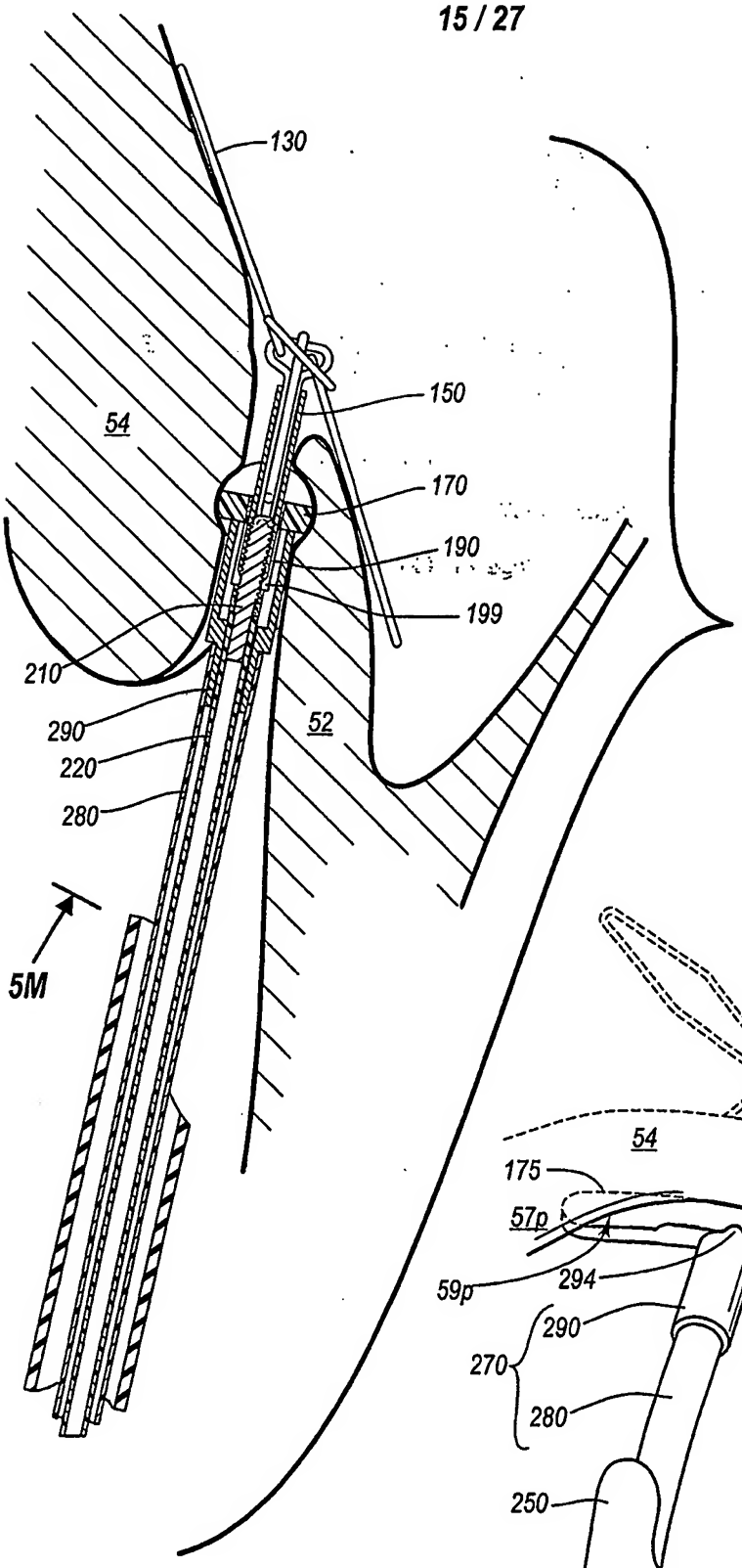
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Fig. 5L

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Fig. 5M

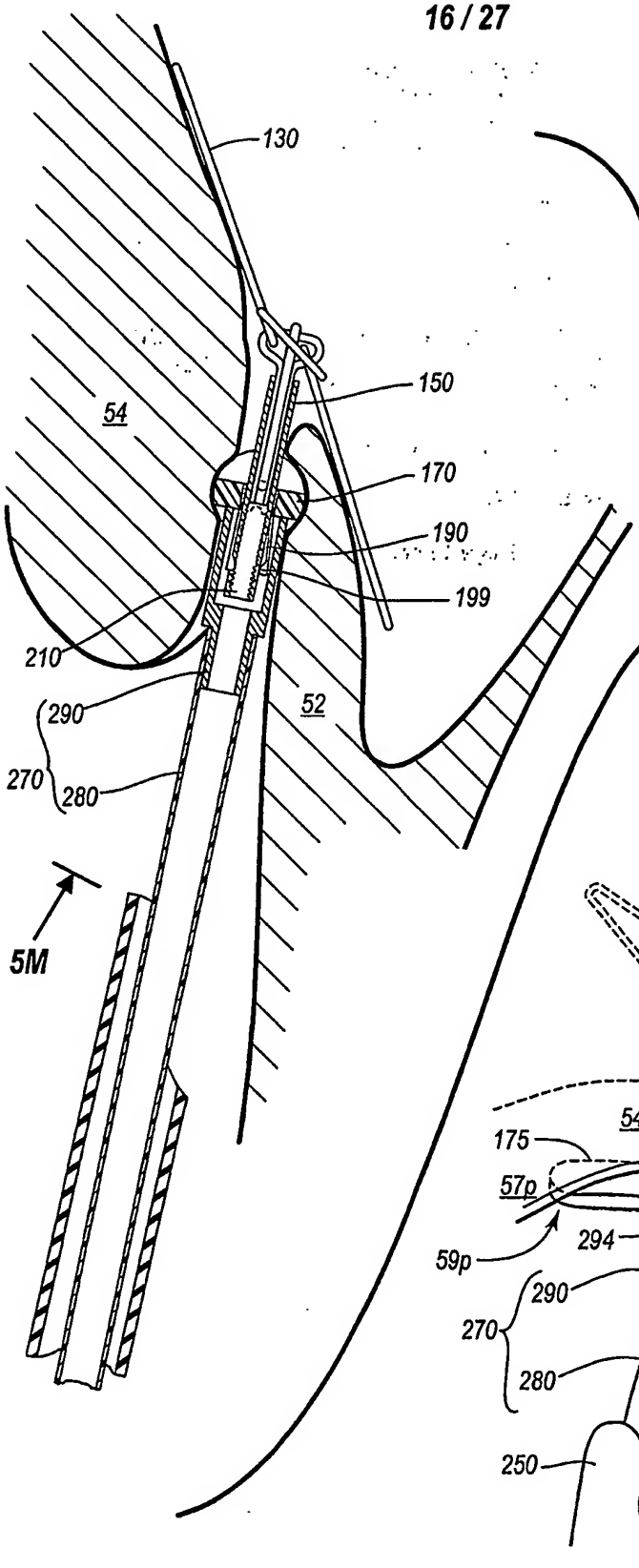
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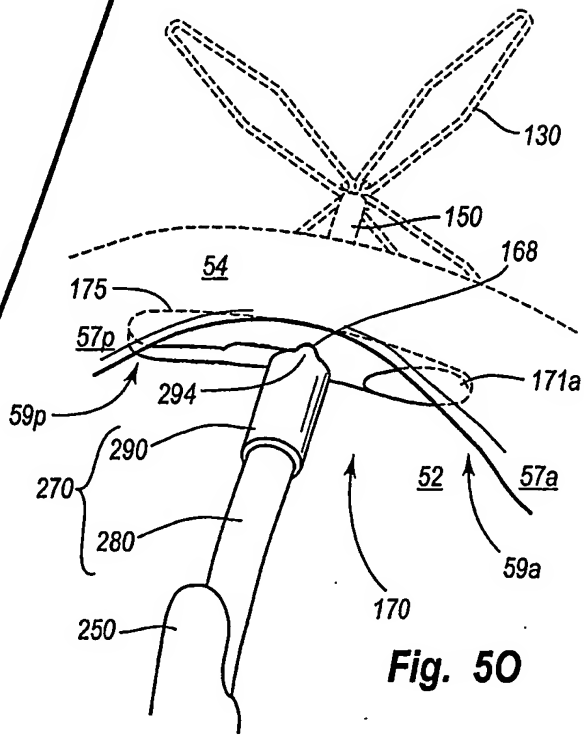
Fig. 5N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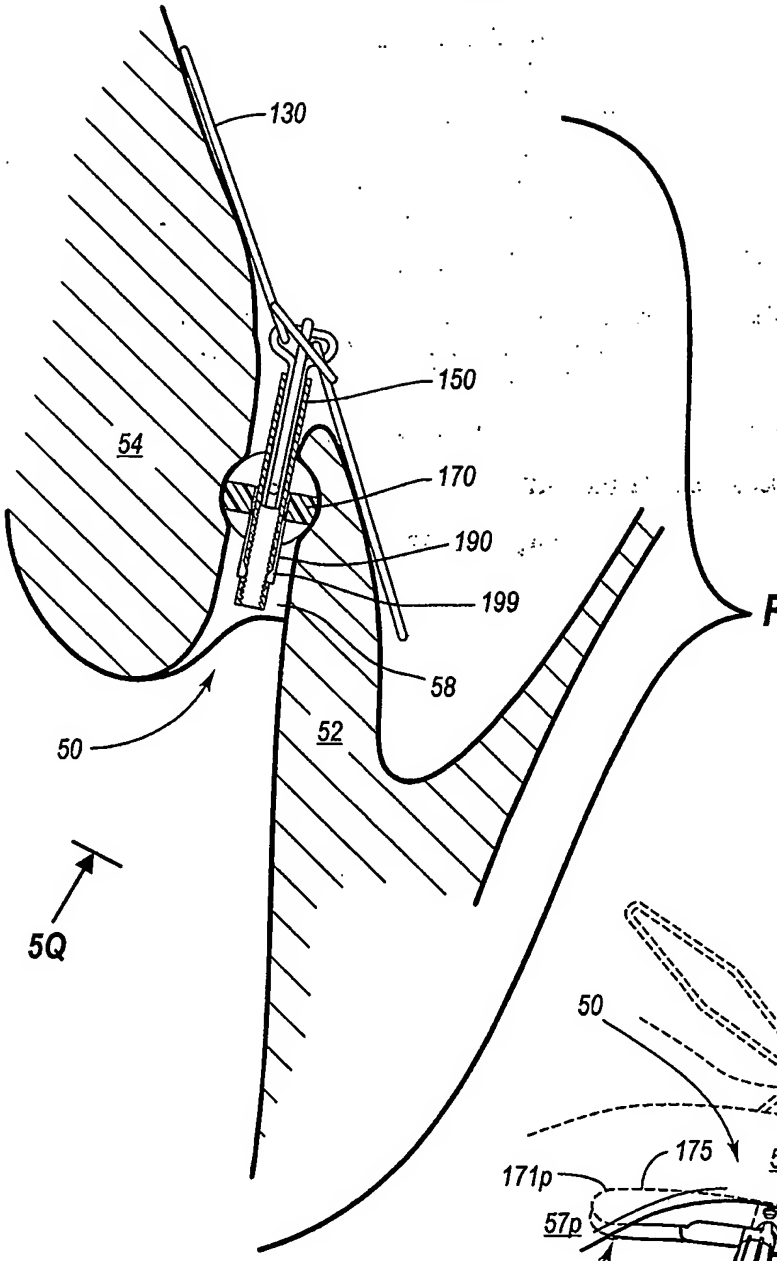
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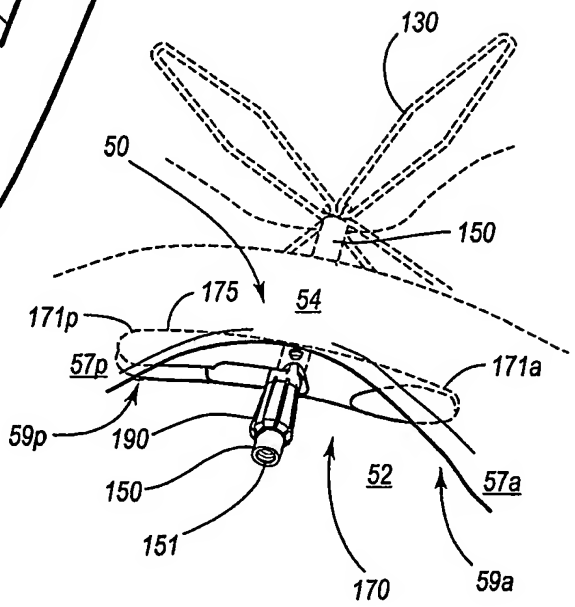
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Fig. 5Q

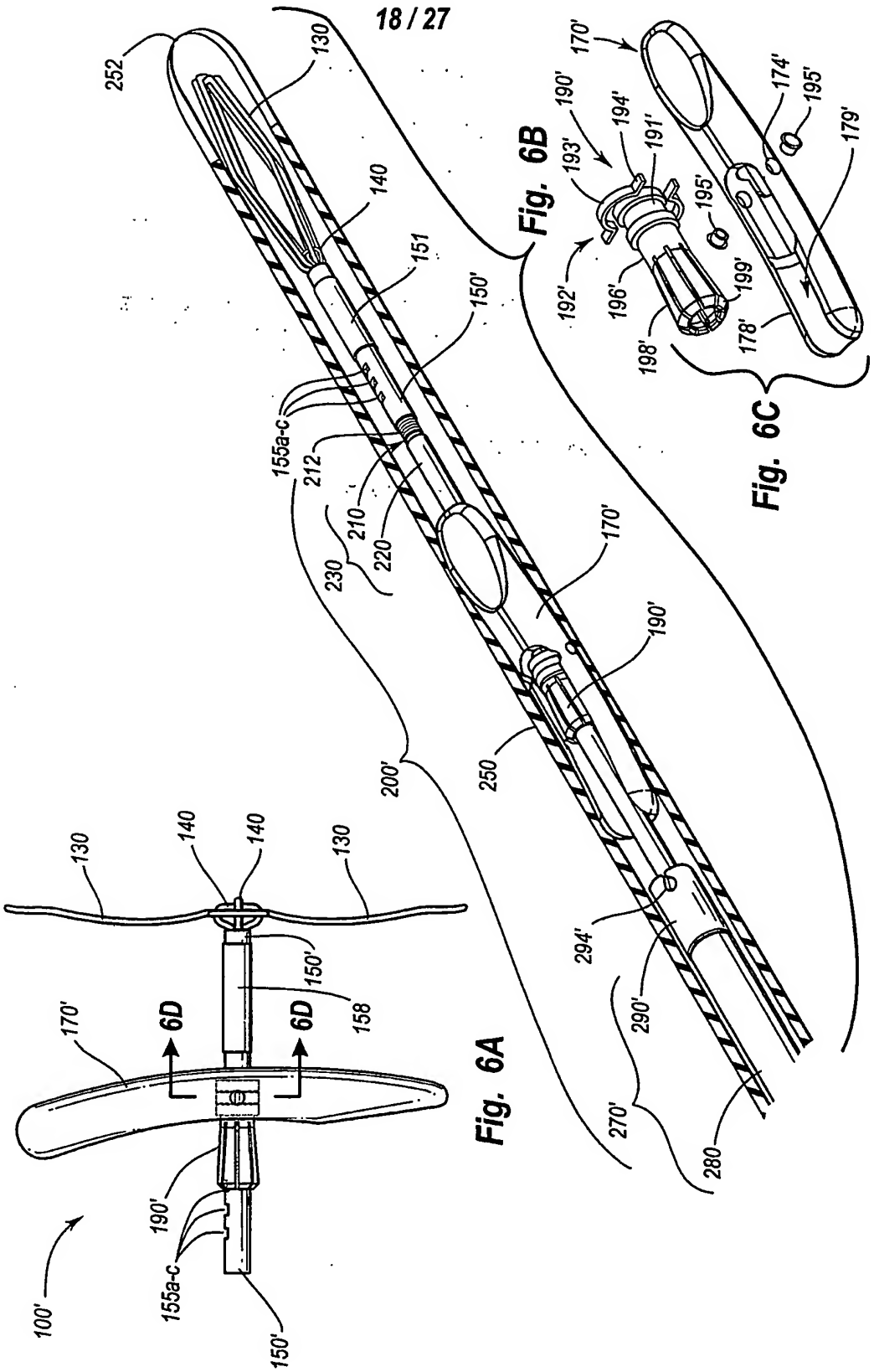
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Fig. 6B
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Fig. 6C

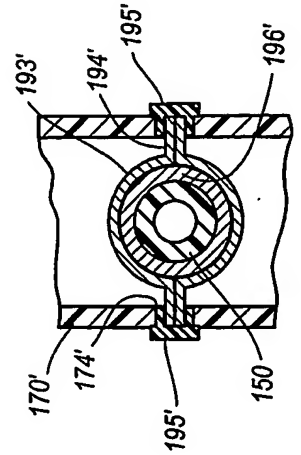


Fig 6D

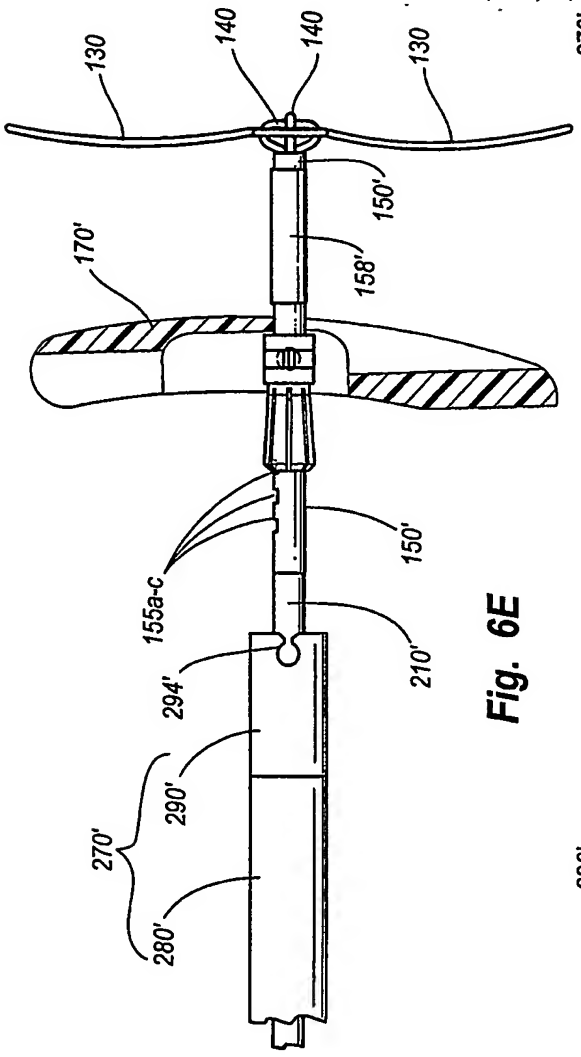
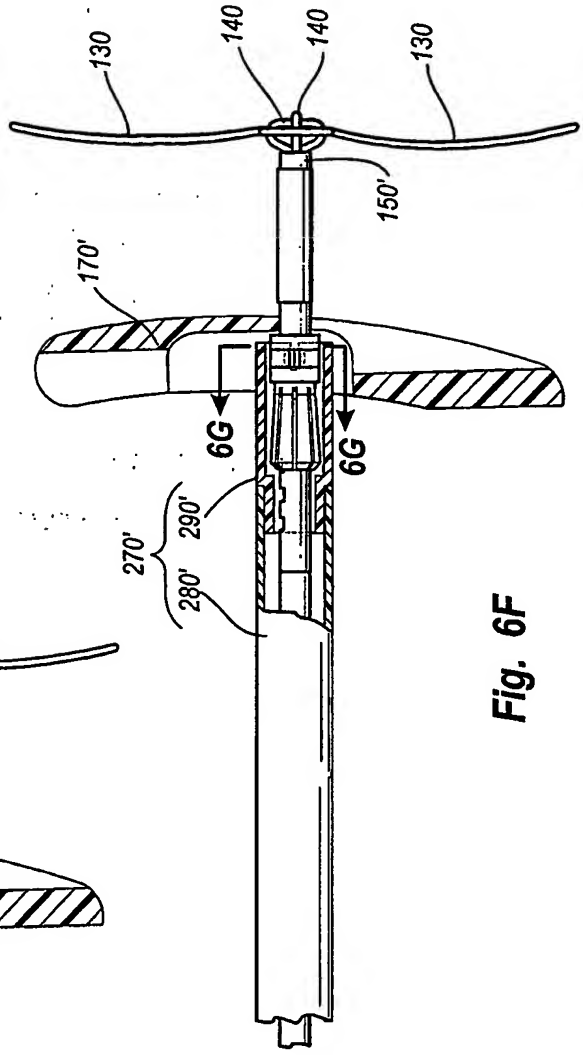


Fig. 6E



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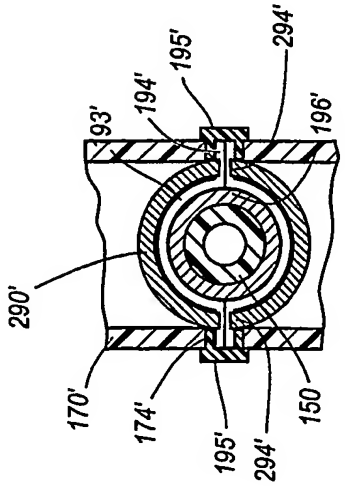

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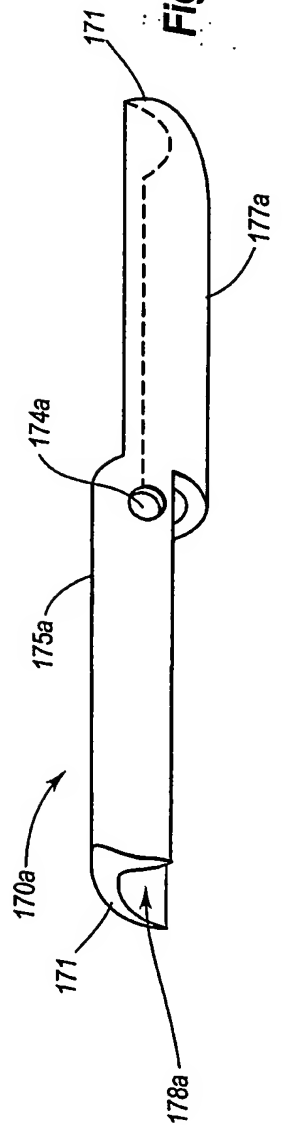

Fig. 7A

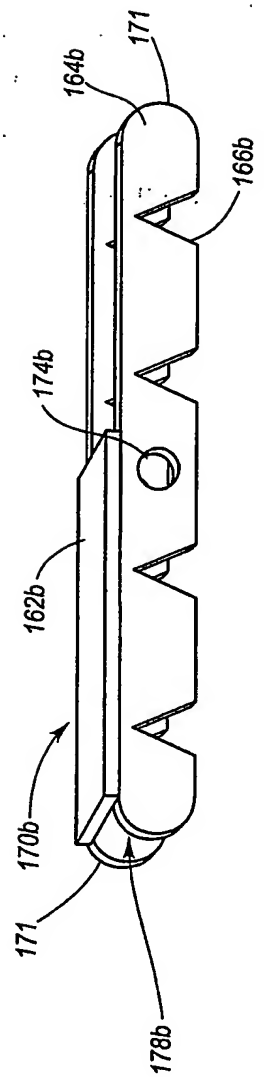

Fig. 7B

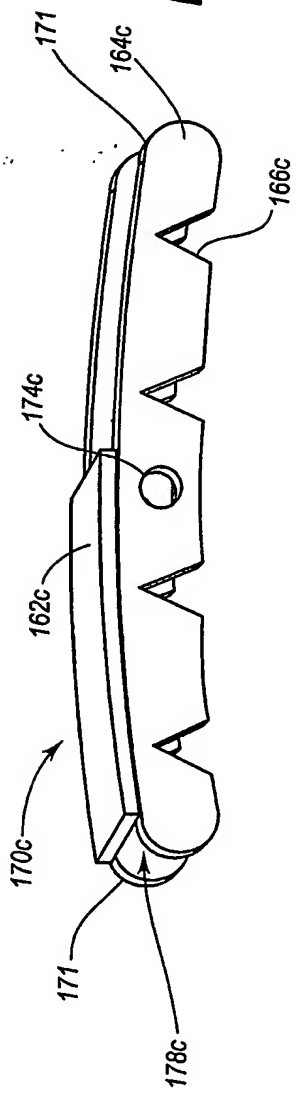

Fig. 7C

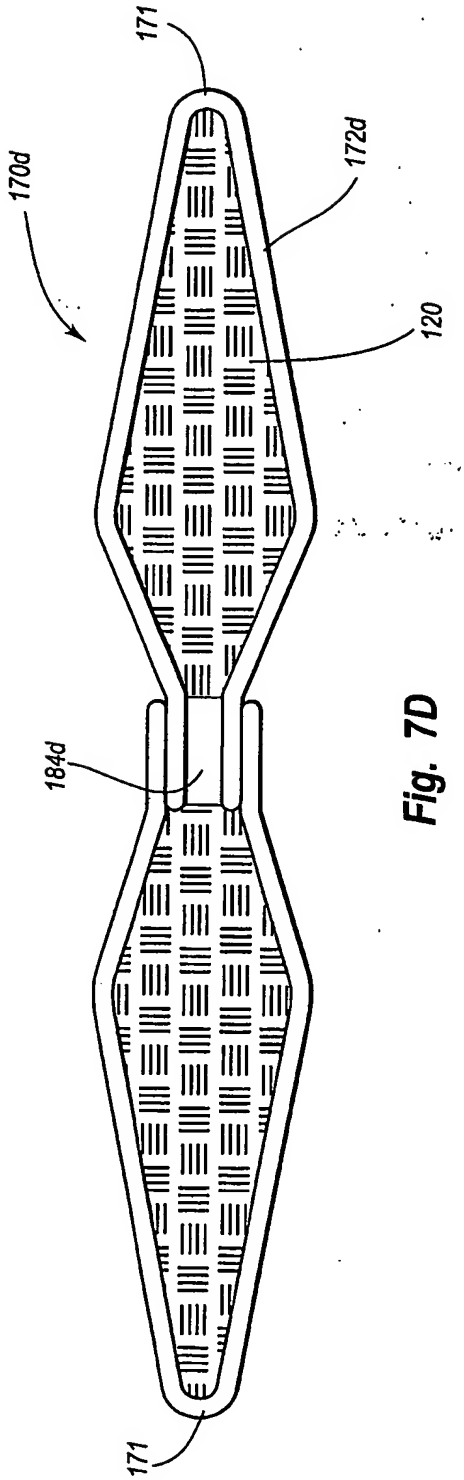

Fig. 7D

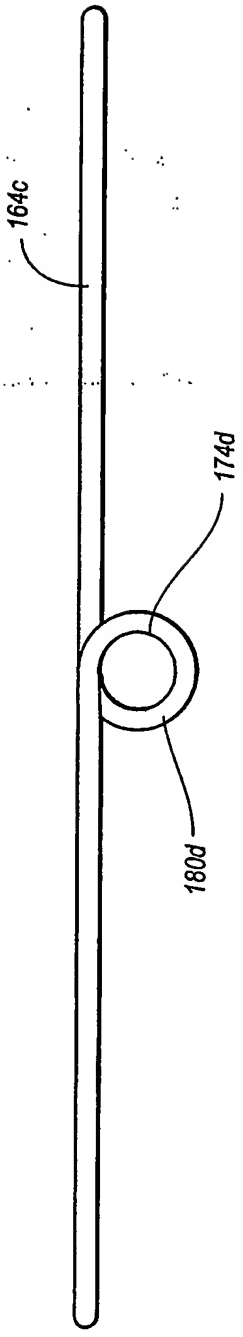

Fig. 7E

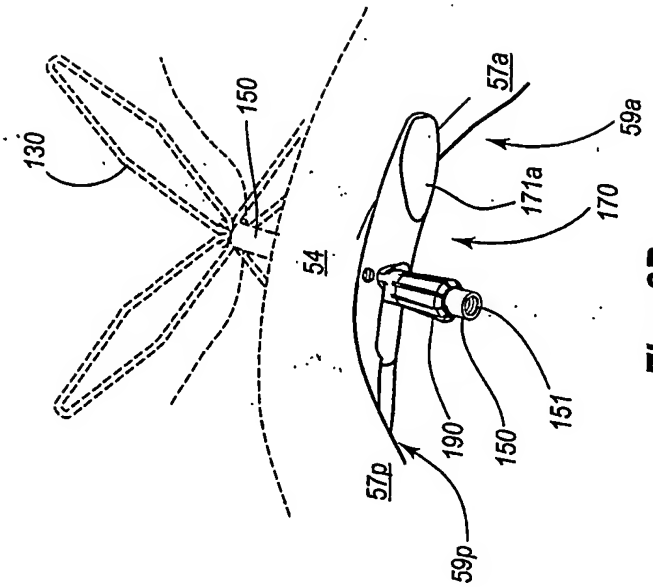
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Fig. 8B

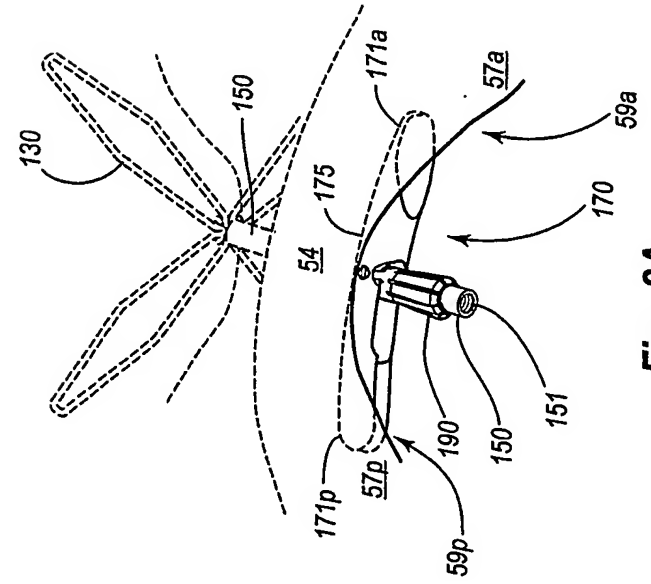
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Fig. 8A

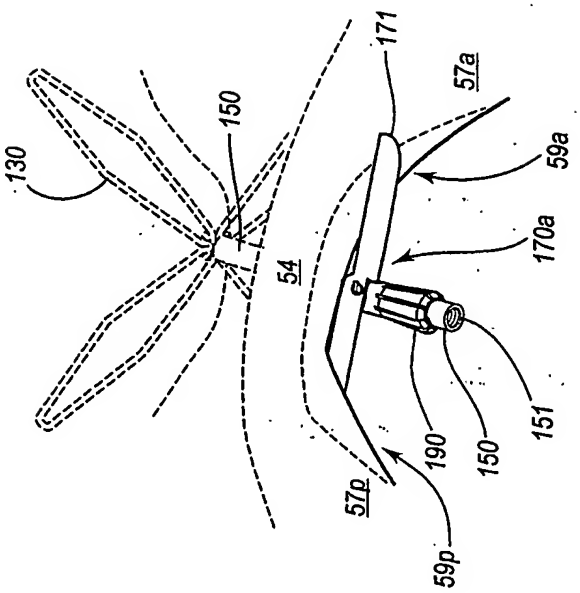
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Fig. 8D

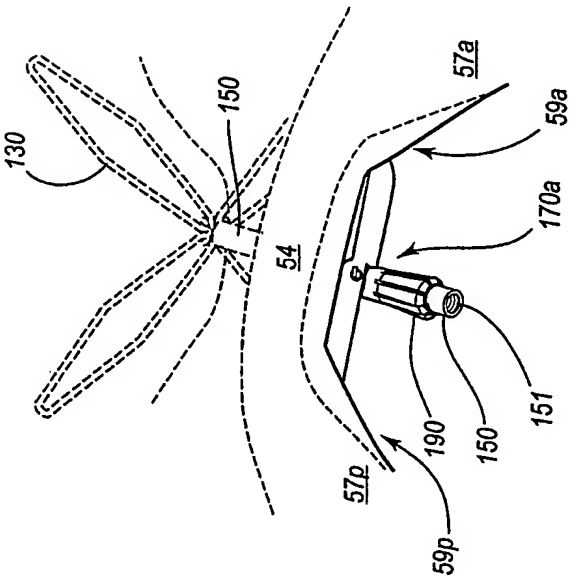
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Fig. 8C

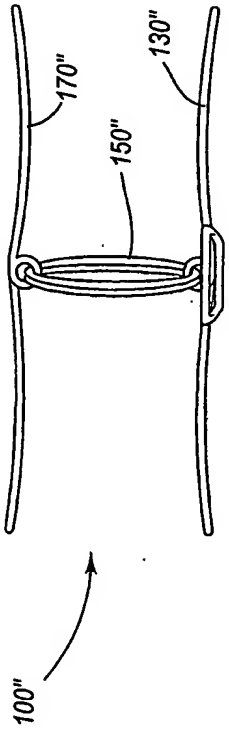

Fig. 10

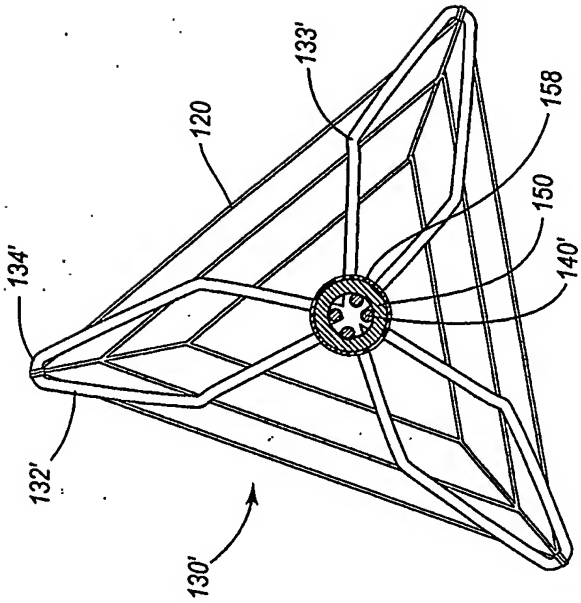

Fig. 9

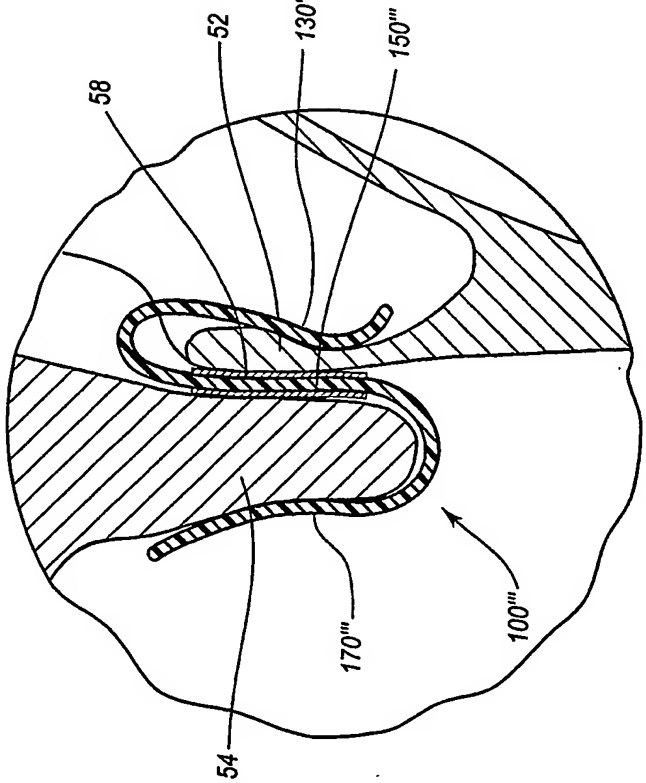

Fig. 11

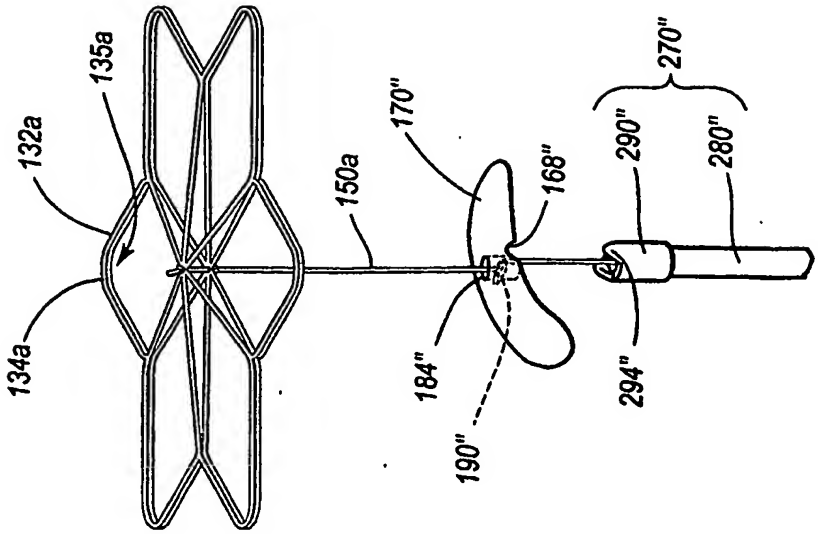

Fig. 12C

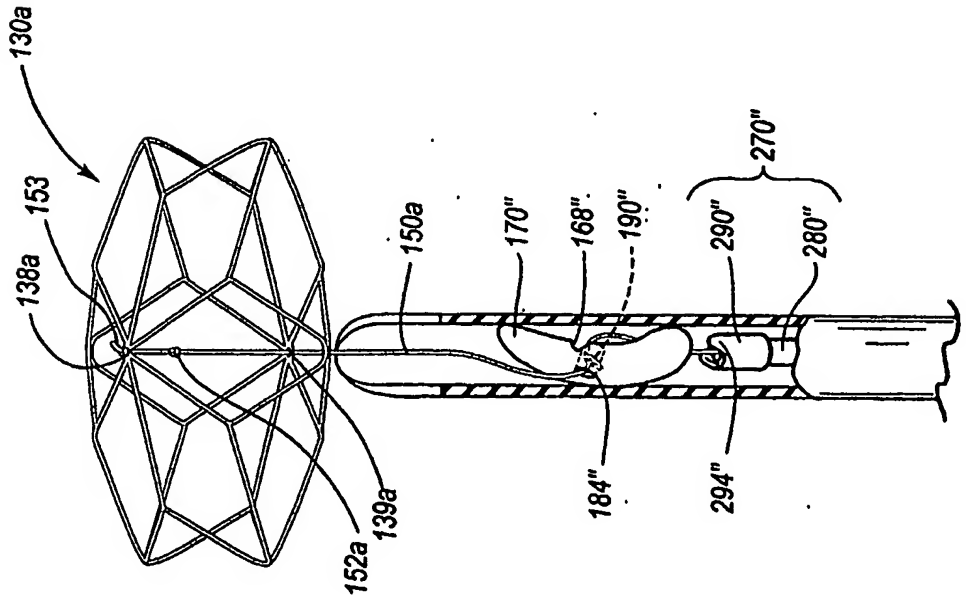

Fig. 12B

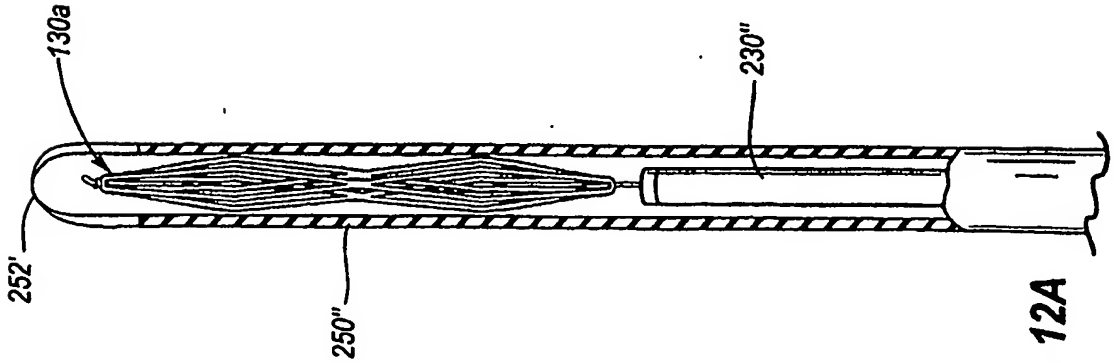

Fig. 12A

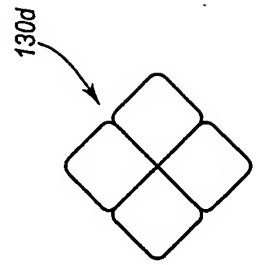

Fig. 13D

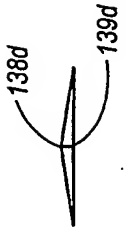

Fig. 14D

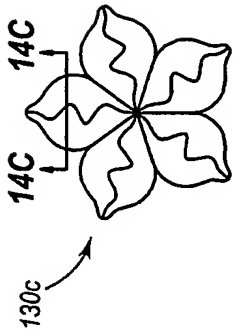

Fig. 13C

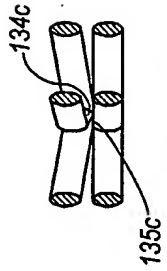

Fig. 14C

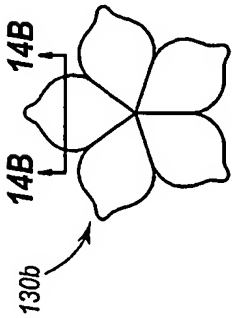

Fig. 13B

Fig. 14B

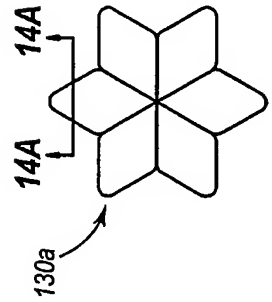

Fig. 13A

Fig. 14A

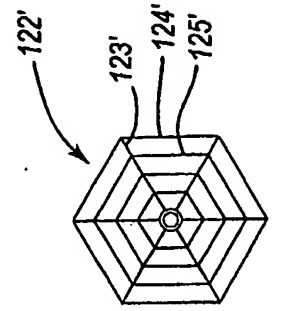

Fig. 15B

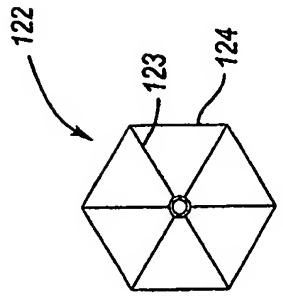

Fig. 15A

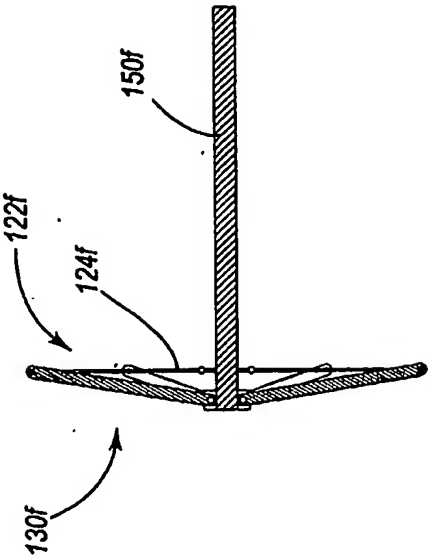

Fig. 15C

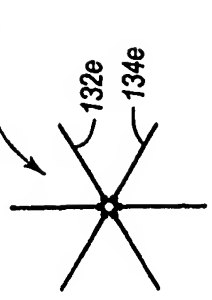

Fig. 13E

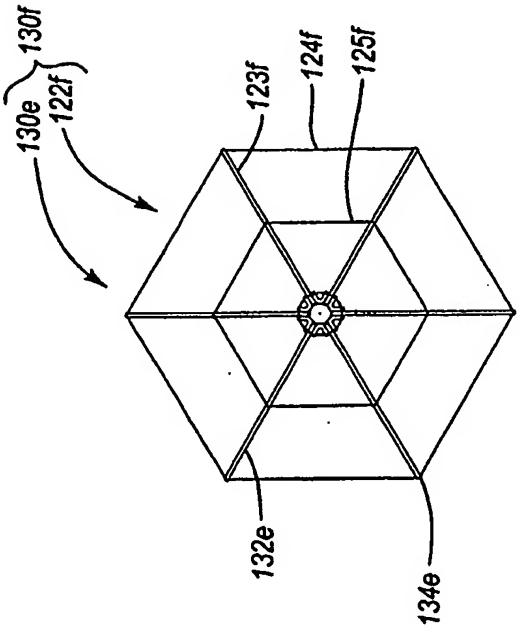

Fig. 13F

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(71) Applicant *(for all designated States except US)*: NMT MEDICAL, INC. [US/US]; 27 Wormwood Street, Boston, MA 02210 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: CHANDUSZKO, Andrzej, J. [US/US]; 311 N. Carriage Lane, Chandler, AZ 85224 (US).

(74) Agents: CAVANAUGH, David, L. et al.; Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, MA 02109 (US).

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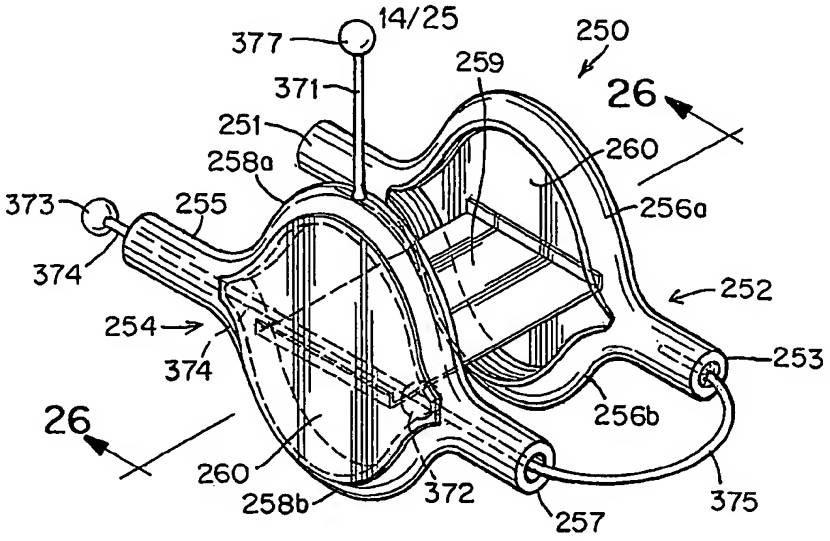
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: PFO CLOSURE DEVICE WITH FLEXIBLE THROMBOGENIC JOINT AND IMPROVED DISLODGEMENT RESISTANCE



(57) Abstract: The present invention provides devices for closing septal defects, such as a patent foramen ovale (PFO). The closure devices (250) include a proximal anchor member (254), a distal anchor member (252), and at least one flexible center joint (259) connecting the two anchor members. According to some embodiments, the proximal and/or distal anchor members may include a generally cylindrical member split along the central portion of its length to form an elongate oval. The proximal and/or distal anchor members may further include a tissue scaffold (260). At least some of the closure devices according to the present invention are repositionable and retrievable.

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— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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PFO CLOSURE DEVICE WITH FLEXIBLE THROMBOGENIC JOINT AND IMPROVED DISLODGEMENT RESISTANCE

Related Applications

[0001] This application is a continuation-in-part of U.S. Application No. 10/326,535, filed December 19, 2002, which claims the benefit of U.S. Provisional Application No. 60/340,858, filed on December 19, 2001.

Field of the Invention

[0002] The present invention relates generally to an occlusion device for the closure of physical anomalies, such as a patent foramen ovale.

Background of the Invention

[0003] A patent foramen ovale (PFO), illustrated in Figure 1, is a persistent, one-way, usually flap-like opening in the wall between the right atrium 10 and left atrium 12 of the heart. Because left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap usually stays closed. Under certain conditions, however, right atrial pressure can exceed left atrial pressure, creating the possibility that blood could pass from the right atrium 10 to the left atrium 12 and blood clots could enter the systemic circulation. It is desirable that this circumstance be eliminated.

[0004] The foramen ovale serves a desired purpose when a fetus is gestating in utero. Because blood is oxygenated through the umbilical chord, and not through the developing lungs, the circulatory system of the fetal heart allows the blood to flow through the foramen ovale as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This functional closure is subsequently followed by anatomical closure of the two over-lapping layers of tissue: septum primum 14 and septum secundum 16. However, a PFO has been shown to persist in a number of adults.

[0005] The presence of a PFO is generally considered to have no therapeutic consequence in otherwise healthy adults. Paradoxical embolism via a PFO is considered in the diagnosis for patients who have suffered a stroke or transient ischemic attack (TIA) in the presence of a PFO and without another identified cause of ischemic stroke. While there is currently no definitive proof of a cause-effect

relationship, many studies have confirmed a strong association between the presence of a PFO and the risk for paradoxical embolism or stroke. In addition, there is significant evidence that patients with a PFO who have had a cerebral vascular event are at increased risk for future, recurrent cerebrovascular events.

[0006] Accordingly, patients at such an increased risk are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly treated with oral anticoagulants, which potentially have adverse side effects, such as hemorrhaging, hematoma, and interactions with a variety of other drugs. The use of these drugs can alter a person's recovery and necessitate adjustments in a person's daily living pattern.

[0007] In certain cases, such as when anticoagulation is contraindicated, surgery may be necessary or desirable to close a PFO. The surgery would typically include suturing a PFO closed by attaching septum secundum to septum primum. This sutured attachment can be accomplished using either an interrupted or a continuous stitch and is a common way a surgeon shuts a PFO under direct visualization.

[0008] Umbrella devices and a variety of other similar mechanical closure devices, developed initially for percutaneous closure of atrial septal defects (ASDs), have been used in some instances to close PFOs. These devices potentially allow patients to avoid the side effects often associated with anticoagulation therapies and the risks of invasive surgery. However, umbrella devices and the like that are designed for ASDs are not optimally suited for use as PFO closure devices.

[0009] Currently available septal closure devices present drawbacks, including technically complex implantation procedures. Additionally, there are not insignificant complications due to thrombus, fractures of the components, conduction system disturbances, perforations of heart tissue, and residual leaks. Many devices have high septal profile and include large masses of foreign material, which may lead to unfavorable body adaptation of a device. Given that ASD devices are designed to occlude holes, many lack anatomic conformability to the flap-like anatomy of PFOs. Thus, when inserting an ASD device to close a PFO, the narrow opening and the thin flap may form impediments to proper deployment. Even if an occlusive seal is formed, the device may be deployed in the heart on an angle, leaving some components insecurely seated against the septum and, thereby, risking thrombus

formation due to hemodynamic disturbances. Finally, some septal closure devices are complex to manufacture, which may result in inconsistent product performance.

[0010] The present invention is designed to address these and other deficiencies of prior art septal closure devices.

Brief Summary of Embodiments of the Invention

[0011] Various embodiments of the present invention are directed to devices for closing septal defects such as PFOs. The closure devices generally include a proximal anchor member, a distal anchor member, and a flexible center joint connecting the two anchor members. The center joint may be one or more sutures. Alternatively, the center joint may be a flexible elastomeric layer, which may promote tissue ingrowth or deliver drugs. The flexible material may also be covered with a biocompatible material to promote adherence to tissue or with growth factors to accelerate tissue ingrowth.

[0012] In accordance with some embodiments of the invention, the closure device is formed of bioresorbable components such that substantially no permanent foreign material remains in the body.

[0013] In accordance with other embodiments of the invention, the proximal and/or distal anchor members of the closure device may include a generally cylindrical member split along the center portion of its length to form an elongate oval when the ends of the member are pressed together. Of course, a variety of cross section shapes in addition to a circular cross section may be used. Such proximal and/or distal anchor members may be two-dimensional or three-dimensional. Such proximal and/or distal anchor members may further include a tissue scaffold.

[0014] In accordance with further embodiments of the invention, mechanisms are provided to collapse the closure device in order to facilitate device delivery, removal and/or repositioning.

[0015] These and other features will become readily apparent from the following detailed description wherein embodiments of the invention are shown and described by way of illustration. As will be realized, the invention is capable of other and different embodiments and its several details may be capable of modifications in

various respects, all without departing from the invention. Accordingly, the drawings and description are to be regarded as illustrative in nature and not in a restrictive or limiting sense.

Brief Description of the Drawings

[0016] FIGURE 1 is a cross-sectional view of a portion of the heart illustrating a PFO;

[0017] FIGURE 2 illustrates a deployed PFO closure device with bioresorbable components in accordance with one or more embodiments of the invention;

[0018] FIGURE 3 illustrates the PFO closure device of FIGURE 2 in a collapsed state for passage through a delivery catheter or sheath;

[0019] FIGURE 4 illustrates a closure device deployed to close a PFO in accordance with one or more further embodiments of the invention;

[0020] FIGURE 5 illustrates a closure device deployed to close the PFO in accordance with one or more further embodiments of the invention;

[0021] FIGURES 6A and 6B are front and side views, respectively, of a PFO closure device in accordance with one or more further embodiments of the invention;

[0022] FIGURES 7A and 7B are front and side views, respectively, of a PFO closure device in accordance with one or more further embodiments of the invention;

[0023] FIGURES 8A and 8B are side and front views, respectively, of the PFO closure device of FIGURE 6 deployed to close a PFO;

[0024] FIGURES 9A illustrates a closure device having a retrieval mechanism in accordance with one or more further embodiments of the invention in a collapsed state for passage through a catheter or sheath;

[0025] FIGURE 9B is a front view of the FIGURE 9A device;

[0026] FIGURES 9C-E illustrate deployment of the FIGURE 9A device;

[0027] FIGURES 9F-H illustrate removal of the FIGURE 9A device;

[0028] FIGURE 10A illustrates a closure device having a retrieval mechanism in accordance with one or more further embodiments of the invention in a collapsed state for passage through a catheter or sheath;

[0029] FIGURE 10B is a front view of the FIGURE 10A device;

[0030] FIGURES 11A and 11B illustrate an anchor member with an elastic hinge in accordance with one or more further embodiments of the invention;

[0031] FIGURE 12 illustrates a PFO closure device made from a single material in accordance with one or more further embodiments of the invention;

[0032] FIGURE 13 illustrates a PFO closure device having inflatable anchor members in accordance with one or more further embodiments of the invention;

[0033] FIGURE 14 illustrates a PFO closure device with a wire connecting the proximal and distal anchor members in accordance with one or more further embodiments of the invention;

[0034] FIGURE 15 illustrates a PFO closure device having a frame member in accordance with one or more further embodiments of the invention;

[0035] FIGURE 16 illustrates a PFO closure device having frame anchor members in accordance with one or more further embodiments of the invention;

[0036] FIGURE 17 illustrates a PFO closure device having frame anchor members in accordance with one or more further embodiments of the invention;

[0037] FIGURE 18 illustrates the FIGURE 17 device in a collapsed state for passage through a catheter or sheath;

[0038] FIGURE 19 illustrates a frame anchor member having metal and polymer components in accordance with one or more further embodiments of the invention;

[0039] FIGURES 20A and 20B illustrate a PFO closure device having anchor members formed from a rolled material in accordance with one or more further embodiments of the invention in rolled and unrolled positions, respectively;

[0040] FIGURES 21A and 21B illustrate an alternate PFO closure device having anchor members formed from a rolled material in accordance with one or more further embodiments of the invention in rolled and unrolled positions, respectively;

[0041] FIGURE 22A illustrates a closure device having frame anchor members and a generally "X" shaped joint member in accordance with one or more further embodiments of the invention;

[0042] FIGURE 22B illustrates the proximal anchor member of the FIGURE 22A device;

[0043] FIGURE 22C illustrates the FIGURE 22A device in a deployed state;

[0044] FIGURE 23 illustrates a closure device having frame anchor members having a generally "+" shaped frame structure in accordance with one or more further embodiments of the invention;

[0045] FIGURE 24 illustrates a closure device having frame anchor members having a generally "G" shaped frame structure in accordance with one or more further embodiments of the invention;

[0046] FIGURE 25 is a perspective view of a two-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention;

[0047] FIGURE 26 is a cross-sectional end view taken along line 26-26 of the two-dimensional closure device of FIGURE 25;

[0048] FIGURE 27 is a schematic view of the two-dimensional closure device of FIGURE 25 deployed at a delivery site *in vivo*;

[0049] FIGURE 28 is a schematic end view of a three-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention;

[0050] FIGURE 29 is a schematic end view of a three-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention;

[0051] FIGURE 30 is a schematic end view of a three-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention;

[0052] FIGURE 31 is a schematic end view of a three-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention;

[0053] FIGURE 32 is a schematic view of the three-dimensional closure device of FIGURE 29 deployed at a delivery site *in vivo*;

[0054] FIGURE 33 is a perspective view of a two-dimensional closure device in accordance with one or more further embodiments of the invention;

[0055] FIGURE 34 is a cross-sectional view taken along line 34-34 of the two-dimensional closure device of FIGURE 33;

[0056] FIGURE 35 is a perspective view of a two-dimensional closure device in accordance with one or more further embodiments of the invention;

[0057] FIGURE 36 is a cross-sectional end view taken along line 36-36 of the two-dimensional closure device of FIGURE 35;

[0058] FIGURE 37 is a schematic perspective view of the two-dimensional closure device of FIGURES 25 and 26 in a collapsed state and inserted into a catheter;

[0059] FIGURES 38-41 are schematic views of a method for delivering a closure device to an intended delivery site *in vivo* according to one or more further embodiments of the invention;

[0060] FIGURE 42 is a schematic view of a method for repositioning a closure device at a delivery site *in vivo* according to one or more further embodiments of the invention;

[0061] FIGURE 43-46 are schematic views of a method for retrieving a closure device from a delivery site *in vivo* according to one or more further embodiments of the invention;

[0062] FIGURE 47 is a perspective view of a two-dimensional closure device in accordance with one or more further embodiments of the invention;

[0063] FIGURES 48A and 48B are perspective views of a two-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention;

[0064] FIGURE 49A is a perspective view of a two-dimensional closure device with anchor members having and elongate oval configuration in accordance with one or more further embodiments of the invention; and

[0065] FIGURE 49B is a schematic view of the two-dimensional closure device of FIGURE 48A deployed at a delivery site *in vivo*.

[0066] FIGURE 50 is a perspective view of a two-dimensional closure device with anchor members having an elongate oval configuration in accordance with one or more further embodiments of the invention; and

[0067] FIGURE 51 is a schematic view of the two-dimensional closure device of FIGURE 49 deployed at a delivery site *in vivo*.

Detailed Description of Embodiments

[0068] Various embodiments of the present invention are directed to methods and devices for closing septal defects such as PFOs, primarily by eliciting a healing response at the defect. The device may have various configurations that, in general, include an anchor member on each side of the septal defect with at least one connecting member between the anchor members that joins the anchor members. The at least one connecting member may have one of several configurations that promotes a healing response in the defect.

[0069] As shown in FIGURE 2, a PFO closure device 18 in accordance with one or more embodiments of the present invention includes a distal anchor component or member 20 (which can be placed on the left atrial side of the PFO), a proximal anchor member 22 (to fix the device in place), a proximal attachment point 24 (for attachment and release from a catheter), and a central connecting member 26 (which can, for example, be a simple suture in accordance with this embodiment).

[0070] In some embodiments, the distal anchor, the proximal anchor, and the connecting member are bioresorbable. These components can be fabricated from either a single bioresorbable polymer or by a laminated composite of two or more materials to provide a unique mix of properties such as, for example, anchor members having stiff centers and flexible edges, and blood contacting surfaces having controlled porosity or surface texture to promote fast and thorough endothelialization, while minimizing thrombosis. In addition, the tissue-contacting surface of the anchors can be designed to provide added stability by, for example, being roughened.

[0071] The distal anchor 20 is an elongated, preferably generally cylindrical, thin bar-like member with rounded, arcuately shaped ends. The tissue contacting surface of the anchor can be generally flattened to increase tissue surface contact. In size, the distal anchor component might, for example, be 15-30 mm long and 2 mm in diameter with a circular cross-section. The proximal anchor 22 can be of similar dimensions and shape, although it can be shorter in overall length.

[0072] Other distal and proximal anchor structures are also possible. For example, the anchors can be formed of a generally flat material rolled to form a cylindrical shape as described below with respect to the embodiments of FIGURES 20 and 21.

[0073] For delivery and deployment, the distal anchor 20 and proximal anchor 22 are positioned to be generally aligned in a longitudinal, end-to-end manner within a delivery sheath or catheter 28 as shown in FIGURE 3. These components, with the flexible connecting member 26, traverse the catheter or delivery sheath in this longitudinal orientation. The catheter or delivery sheath is inserted between septum primum and septum secundum into the left atrium 18, and the distal anchor component 20 is ejected. Then, the catheter or delivery sheath 28 is withdrawn into the right atrium, and the proximal anchor 22 is ejected. The flexible central connecting member 26 extends between septum primum and septum secundum to join the distal anchor 20 and the proximal anchor 22. Once ejected, the distal anchor and proximal anchor generally self-orientate to be essentially perpendicular to the axis of the central connecting member and in generally parallel planes to one another. The exact orientation will be governed by the individual patient's anatomy. The terms "withdrawn" and "ejected" are relative and are intended to generically describe the relative movement of the device with respect to the delivery catheter.

[0074] An alternate delivery method for this device can be to deploy it directly through the septum primum as opposed to through the PFO.

[0075] The method of attaching the central connecting member 26 to the anchor and stop mechanism 22 to permit the distal anchor and the proximal anchor to be drawn together could be, for example, via a friction fit or via a slip knot on the central connecting member. If a slip knot is used, the free end of the suture proximal to the knot can be held remotely and released after the knot has been placed in the appropriate location.

[0076] In one or more alternate embodiments of the invention shown in FIGURE 4, the central connecting member 26 is mounted to permit free sliding movement of the proximal anchor 22 relative to the central connecting member 26. A biasing spring 30, which may be an expandable coil spring, can be formed at the outer end of the central connecting member 26 to bias the proximal anchor toward the distal anchor when both are deployed from the catheter or sheath.

[0077] In the embodiments illustrated in FIGURES 4 and 5, a metallic component may be used as the central connecting member 26 in order to provide an appropriate stop and apply compression force to the proximal anchor 22. The metallic

component could be a piece of shape memory wire that has one end molded or laminated into the distal anchor component 20. In FIGURE 4, the proximal anchor 22 slides on the central connecting member 26, and once it is deployed, the biasing spring 30 formed on the end of the shape memory wire expands to bias the proximal anchor 22 toward the distal anchor 20.

[0078] In the FIGURE 5 embodiment, a shape memory wire forms a hook type anchor 32 made from two wires that exit through the center of the proximate anchor and curve in opposite directions when expanded to draw the proximate anchor toward the distal anchor.

[0079] While the embodiments of FIGURES 4 and 5 can leave a permanent foreign body when the bioresorbable components dissolve (if, for example, a metallic component is used as the central connecting member 26), one advantage of these devices is that no thrombogenic tissue scaffold (usually a vascular material) is placed on the left atrial side. Thrombus forming on the LA side of a PFO closure device can be released into the systemic circulation causing an embolic event within the coronary arteries, cerebral circulation, or distally in the vasculature, and most vascular graft materials utilized to close PFOs are highly thrombogenic.

[0080] The PFO closure devices may need to be capable of x-ray visualization and use with radiopaque fillers or marker bands, which may be fabricated from noble metals such as platinum or gold. These markers can be attached using a variety of common methods such as, for example, adhesive bonding, lamination between two layers of polymer, or vapor deposition.

[0081] FIGURES 6A and 6B illustrate a closure device 50 in accordance with one or more further embodiments of the invention. The device 50 includes proximal and distal anchor members 52, 54 connected with a flexible (and preferably stretchable elastomeric) center joint or connecting element 56. The anchor members 52, 54 are preferably cylindrical in shape with rounded ends. In size, the distal anchor member 54 might, for example, be about 15-30 mm long and about 2 mm in diameter with a circular cross-section. The proximal anchor 52 can be of similar dimensions and shape, although it can be shorter in overall length. The anchor members 52, 54 are preferably made from a relatively rigid (preferably bioresorbable) polymer (regular or shape memory), or biological tissue. Biocompatible metal can also be used.

[0082] Other distal and proximal anchor structures are also possible. For example, the anchors can be formed of a generally flat material rolled to form a cylindrical shape as described below with respect to the embodiments of FIGURES 20 and 21.

[0083] The center joint 56 of the FIGURE 6 device (as well as the center joints of the devices shown in FIGURES 7-10, 12-18, and 21-24) are preferably elastomeric and resilient and are made from thrombogenic or inflammatory materials including, for example, polyester, biological tissue, bioresorbable polymer, small diameter springs (*e.g.*, Nitinol springs), or spongy polymeric material. Alternatively, the center joint can be made of multiple strands of material 58 such as, for example, polymer fibers as shown in the closure device 60 of FIGURES 7A and 7B. The center joint can be textured, porous or in a form of a single or double-sided hook material such as Velcro. These kinds of surfaces produce inflammatory responses and therefore, promote faster tissue ingrowth and faster defect closure. The entire device or parts of it can be made from bioresorbable polymers.

[0084] FIGURE 8A and 8B are front and side views, respectively, of the device 50 in a PFO defect. The proximal and distal anchor members 54, 52 are longer than the defect width, thereby inhibiting the device from being embolized.

[0085] In accordance with further embodiments of the invention, a closure device can include a delivery/removal mechanism to facilitate device delivery, removal or repositioning. A device 70 shown in FIGURES 9A and 9B includes a removal string 72 and a delivery string 74. The removal string is movably secured and slides freely inside of the proximal anchor member 76. The string extends from one end of the proximal member 76 and is fixed to an opposite end of the distal anchor member 78. By pulling on the free end of the removal string 72, the whole device 70 can be collapsed and pulled into the delivery sheath 79 as shown in FIGURE 9A. The strings can, for example, be sutures or wires such as Nitinol wire.

[0086] The delivery and removal strings are manipulated separately in order to deploy or remove the device. FIGURES 9C-E illustrate device deployment using the delivery string 74, which is preferably attached generally to the center of the proximal anchor member 76. The delivery sheath 79 containing the device 70 is first inserted between the septum primum and septum secundum into the left atrium as shown in

FIGURE 9C. As shown in FIGURE 9D, the distal anchor 78 is then ejected from the delivery catheter 79. Tension is then applied to the delivery string 74, and the delivery sheath is withdrawn into the right atrium and the proximal anchor 76 is ejected. Applying tension to the delivery string enables the proximal anchor 76 to be properly deployed in the right atrium, and keeps the anchor 76 from being ejected into the left atrium. Upon successful deployment of the device 70, both strings are released and the delivery system is withdrawn. No tension is applied to the removal string during delivery.

[0087] FIGURES 9F-H illustrate removal of the device 70. As shown in FIGURE 9F, tension is applied to the removal string, while the delivery sheath 79 is moved toward the device 70. The applied tension causes the proximal anchor 76 to be withdrawn into the delivery sheath as shown in FIGURE 9G. The distal anchor 78 is also withdrawn into the delivery sheath as further tension is applied to the removal string. The device can then be redeployed if desired or removed.

[0088] Alternatively, the delivery string 74 can be omitted, and the removal string 72 can be used for both device deployment and removal. The delivery sheath 79 containing the closure device is first inserted between septum primum and septum secundum into the left atrium in a similar manner to that shown in FIGURE 9C. The distal anchor 78 is then ejected from the delivery catheter 79 in a similar manner to that shown in FIGURE 9D. Tension is applied to the removal string 72, and the delivery sheath is withdrawn into the right atrium, and the proximal anchor 76 is ejected. Applying tension to the removal string enables the proximal anchor 76 to be properly deployed in the right atrium and keeps the proximal anchor 76 from being ejected into the left atrium. The elasticity of the center joint connecting the anchor members helps properly position the proximal anchor at the defect. Upon successful deployment of the closure device, the string 72 is released and the delivery system is withdrawn.

[0089] As shown in FIGURES 10A and 10B, in another embodiment, strings 80 (suture, Nitinol wire, etc.) are attached to both ends of the proximal anchor member 82 of a closure device 84. Both anchor members are flexible and can fold as shown in FIGURE 10A in order to be delivered to or removed from the defect.

[0090] In accordance with a further embodiment of the invention, as shown in FIGURES 11A and 11B, each of the proximal and distal anchor members can include two elements 90 separated by an elastic hinge 92. The elastic hinge 92 can facilitate folding of the members as shown in FIGURE 11B. The hinge 92 can be molded or made from a material such as, for example, Nitinol or other shape memory materials, which can be a different material from the elements 90.

[0091] In accordance with some embodiments of the invention, an entire closure device can be made from a single sheet of a material as shown, for example, in the closure device 100 of FIGURE 12. Two opposite ends of the sheet can be rolled to form the proximal and distal anchor members. Glue or heat bonding can be used to maintain the rolled-up configuration of the anchor members 102, 104.

[0092] As shown in FIGURE 13, in accordance with some further embodiments of the invention, one or both anchor members 110, 112 of a closure device 114 can be inflatable. The anchor members can be inflated with, for example, saline or other physiological fluid during or before the delivery of the device. A tube 116 can communicate with cavities in the anchor members. An inlet 118 can be provided at one of the members for introducing fluid therein.

[0093] In accordance with some further embodiments of the invention, a wire 120 such as, for example, an S-shaped wire, can be provided to connect the proximal and distal anchor members 122, 124 of a device 126 as shown in FIGURE 14. The wire can be used to provide additional clamping force while the device is in a PFO defect. Other wire shapes are also possible.

[0094] In accordance with further embodiments of the invention, one or more frame structures can be used as the anchor members of a closure device. For example, FIGURE 15 shows a closure device 130 having a frame structure 132. Also, FIGURE 16 shows a closure device 136 having frames 138, 139. The frames can be, for example, a metal (*e.g.*, Nitinol wire) or polymer frame.

[0095] FIGURES 17-19 illustrate closure devices in accordance with some further embodiments of the invention. A closure device 140 shown in FIGURE 17 includes anchor members 142, 144 having a frame structure. The frame shape can be polygonal as shown in the figure or it can alternatively be a circular shape. Other

frame shapes are also possible as, for example, will be described below with respect to FIGURES 22-24.

[0096] A recovery suture can be attached to opposite ends of the proximate anchor member 142 to collapse the anchors for delivery in a catheter 146 as shown in FIGURE 18 or for retrieval or repositioning. The anchor members can be made from a metal, preferably Nitinol, or polymers. Alternatively, as shown in FIGURE 19, an anchor member 148 can include both metal and polymer components.

[0097] In accordance with one or more further embodiments of the invention, the distal and proximal anchors can be formed of a flat sheet-like member rolled to form a cylindrical shape as shown, for example, in the device 170 of FIGURE 20A. The anchors 172, 174 can unroll to form sheet-like members when deployed, as shown generally in FIGURE 20B. The sheet-like member can be made of a material having shape memory properties such as, for example, shape memory polymeric materials. Alternately, the sheet-like member can include metal struts made of shape memory metals such as, for example, Nitinol or Nitinol alloys. The shape memory materials allow the device to be delivered in a delivery sheath or catheter with the anchors in the rolled configuration of FIGURE 20A. The anchors attain the sheet-like geometry of FIGURE 20B once deployed due to their shape memory properties. The anchor members 172, 174 can be connected to each other with a connecting member 176, which can, for example, be a suture similar to that used in the FIGURE 2 device.

[0098] FIGURES 21A and 21B illustrate a closure device 180 having rolled anchor members 182, 184, which are similar to the anchor members 172, 174 of the device of FIGURES 20A and 20B. The anchors 182, 184 are connected to each other by a connecting member or joint 186, which can be a sheet of flexible material similar to the connecting members previously described with respect to FIGURES 6 and 7.

[0099] FIGURE 22A illustrates a closure device 200 in accordance with one or more further embodiments of the invention. The device 200 includes distal and proximal anchor members 202, 204, each of which has a polygonal or circular frame structure. The anchor members are connected by a connecting member 206, which can be made from a flexible material similar to that previously described in connection with FIGURES 6 and 7. The connecting member 206 can be made of two sheets of flexible material connected at their centers, generally forming an "X" shape in the side

view of the device. As shown in FIGURE 22B, the proximal anchor member 204 can include one or more recovery wires or sutures attached to the frame structure for use in device deployment of recovery. FIGURE 22C illustrates the device 200 as deployed.

[0100] FIGURES 23 and 24 illustrate closure devices 220, 230, respectively, in accordance with further embodiments of the invention. Each device 220, 230 includes distal and proximal anchor members having a frame structure. The anchor members are connected by a flexible joint 222, which can be made from a flexible material similar to that previously described in connection with FIGURES 6 and 7. The FIGURE 23 device 220 includes distal and proximal anchor members 224, 226 generally having a "+" shape. The FIGURE 24 device 230 includes distal and proximal anchor members 232, 234 generally having a "G" shape.

[0101] In still further embodiments of the closure device 250 according to the present invention, the distal and/or proximal anchor members 252 and 254, respectively, may be formed of cylindrical structures, split along the central portion of their length to provide elongate ovals (*i.e.*, an "open-mouthed" configuration) as shown in FIGURES 25-27. In this elongate oval configuration, arcs 256 and 258 are joined by ends 251, 253 and 255, 257, respectively (FIGURE 25). This configuration increases the size and surface area of the anchor member, thereby improving the dislodgement resistance of the closure device 250. As used herein, "dislodgement resistance" refers to the ability of a closure device to resist the tendency of the force applied by the unequal pressures between the right atrium 10 and the left atrium 12 (*i.e.* the "dislodging force") to separate the closure device from the septal tissue. Generally, a high dislodgement resistance is desirable.

[0102] Distal and/or proximal anchor members 252 and 254 having this elongate oval configuration may be either two-dimensional (FIGURES 25-27) or three-dimensional (FIGURES 28-32). As shown in FIGURE 28, in the three-dimensional configuration, the arcs 258a and 258b of proximal anchor member 254 are predisposed to bend at an angle θ from the plane A of the two-dimensional proximal anchor member 254. Arcs 258a and 258b may bend at an angle θ either toward or away from center joint 259 (FIGURES 29 and 30, respectively). In particular embodiments, both distal anchor 252 and proximal anchor 254 are three-dimensional. In such embodiments, arcs 256a and 256b of distal anchor member 252 and arcs 258a

and 258b of proximal anchor member 254 may bend at the same angle θ or at different angles θ_{distal} and $\theta_{proximal}$, respectively. Further, arcs 256a, 256b and 258a, 258b may bend toward center joint 259 (FIGURE 29), away from center joint 259 (FIGURE 30), or in opposite directions (*i.e.,* one toward center joint 259 and one away from center joint 259, as shown in FIGURE 31). As shown in FIGURES 28-32, arcs 256a, 256b and 258a, 258b include a straight bend; however, arcs 256a, 256b and 258a, 258b may also include a curved bend such that they are concave or convex. One skilled in the art will further recognize that, in a three-dimensional configuration, ends 251, 253 and 255, 257 may also be bent as described above for arcs 256a, 256b and 258a, 258b.

[0103] In some clinical applications, a three-dimensional configuration of distal anchor member 252 and/or proximal anchor member 254 may be particularly advantageous. For example, septum primum 14 and septum secundum 16 are typically of disparate thickness, as shown in FIGURE 32. Consequently, the septal tissue in the right atrium 10 is characterized by a step-like surface (indicated by line L_{RA}). The septal tissue in the left atrium 12 may also be characterized by a similar step-like surface (indicated by line L_{LA}). Insertion of a closure device including a two-dimensional anchor into a PFO surrounded by such step-like septal tissue often results in undesirable seating of that anchor member against the septal tissue, in that at least one arc of each anchor member does not contact the septal tissue, as shown in FIGURE 27. However, the angled arcs of a three-dimensional anchor member may more closely approximate the step-like surface of the septal tissue, as shown in FIGURE 32. Thus, in certain clinical applications, the use of a closure device including a three-dimensional distal anchor member 252 and/or proximal anchor member 254 may provide improved seating of the device 250 against the septal tissue and, correspondingly, a reduced profile of the device 250 and more effective closure of the PFO. As used herein, "profile" refers to the degree to which closure device 250 extends away from the septal tissue (*i.e.,* septum primum 14 and septum secundum 16) and is exposed in the atria. A device having a "low profile" is closely seated against the septal tissue and extends only slightly, if at all, into the atria. A device having a "high profile" extends away from the septal tissue and into the atria. Generally, a device having a low profile is desirable because it is less thrombogenic *in vivo*. One

skilled in the art will be capable of determining those clinical applications in which the use of three-dimensional anchor members is appropriate.

[0104] Either or both of distal anchor member 252 and proximal anchor member 254 having the above-described elongate oval configuration may include a tissue scaffold 260 extending between their two arcs 256a, 256b and 258a, 258b, respectively, as shown in FIGURE 25. The inclusion of tissue scaffold(s) 260 augments the area of septal tissue covered by the anchor members 252 and/or 254. Consequently, device 250 provides improved closure of the PFO. Moreover, tissue scaffold 260 promotes encapsulation and endothelialization of the septal tissue, thereby further encouraging anatomical closure of the PFO. The tissue scaffold 260 may be formed of any flexible, biocompatible material capable of promoting tissue growth, including but not limited to, polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, other natural materials (*e.g.*, collagen), or combinations of the foregoing materials. For example, the tissue scaffold 260 may be formed of a thin metallic film or foil, *e.g.*, a nitinol film or foil, as described in United States Patent Application No. 2003/0059640 (the entirety of which is incorporated herein by reference).

[0105] Distal anchor member 252 and proximal anchor member 254 may be connected by a flexible center joint 259 (FIGURE 25). As previously described, in at least some embodiments, center joint 259 includes a stretchable elastomeric material. In at least some embodiments, center joint 259 includes a thrombogenic or inflammatory material, such as polyester, biological tissue, bioresorbable polymer, small diameter springs, *e.g.*, nitinol springs, spongy polymeric material, or combinations of the foregoing materials. In at least some embodiments, center joint 259 is textured, porous, or in the form of a single- or double-sided hook material, such as Velcro. These types of surfaces produce inflammatory responses and, therefore, promote faster tissue ingrowth and defect closure. In particular embodiments and as shown in FIGURE 25, center joint 259 is formed of a deformable or expandable film, such as those disclosed in United States Patent Application Nos. 2002/0165600 and 2002/0165576 (both of which are incorporated herein by reference). For example, center joint 259 may be formed of a shape memory film (*e.g.*, nitinol film) or a

polymeric film. Small openings 471, *e.g.*, slits or holes, may be cut in the film such that, as the film expands upon deployment *in vivo*, the openings 471 also expand (FIGURES 48A and 48B). In this manner, the center joint 259 is rendered more flexible and capable of expanding significantly in length without placing excessive strain on the closure device (FIGURE 48B). In some embodiments, the closure device 250 may include two flexible center joints 259a and 259b (FIGURE 33).

[0106] Center joint 259 may be of various shapes and sizes depending upon the particular anatomy of the patient's septal tissue. For example, as shown in FIGURE 25, center joint 259 may be generally rectangular. In other embodiments, and as shown in FIGURE 35, center joint 259 may be shaped generally as an "X" or hourglass when in its relaxed configuration. Removing material from the sides of center joint 259 to form an hourglass shape increases its flexibility *in vivo*. The amount of material removed from the sides of a rectangular center joint 259 to form an hourglass shape will vary depending upon the particular application. According to some embodiments, between one-third and two-thirds of a rectangular center joint 259 will be removed to form the corresponding hourglass center joint 259. In particular embodiments, approximately one-half of a rectangular center joint 259 will be removed to form the corresponding hourglass center joint 259. In determining the precise amount of material to remove from the sides of a rectangular center joint 259 to form an hourglass center joint 259, a sufficient portion of center joint 259 must be retained to promote the healing response of the septal tissue that it contacts *in vivo*. One skilled in the art will be able to determine the precise amount of material that may be removed from a rectangular center joint 259 to form an hourglass center joint 259 suitable to the patient's septal anatomy while sufficiently maintaining the ability of center joint 259 to promote the healing of the septal tissue.

[0107] Center joint 259 may be connected to distal and proximal anchor members 252 and 254, respectively (FIGURES 35 and 36), or, if present, to tissue scaffolds 260 (FIGURE 25). Center joint 259 may connect to tissue scaffolds 260 at their centers (FIGURE 25), at a location on their peripheries (FIGURES 33 and 34), or somewhere in between (FIGURE 48A). In particular embodiments, center joint 259 is connected at a location between the center and a periphery of tissue scaffold 260 on distal anchor member 252 and at a location between the center and opposite periphery

of tissue scaffold 260 on proximal anchor member 254 (FIGURE 48A) so as to more closely approximate the angled, tunnel-like anatomy of the PFO and reduce the profile of closure device 250 *in vivo* (FIGURE 48B). For example, as shown in FIGURES 48A and 48B, center joint 259 may be connected to the tissue scaffold 260 of distal anchor member 252 at a location between the center of the tissue scaffold 260 and the arc 256a and connected to the tissue scaffold 260 of proximal anchor member 254 at a location between the center of tissue scaffold 260 and the arc 258b.

[0108] A closure device including a distal anchor member 252 and/or proximal anchor member 254 having an elongate oval configuration may be deployed or retrieved if arcs 256a, 256b and/or 258a, 258b, respectively, are collapsed to reduce the profile of closure device 250 such that it may be drawn into and contained within a delivery or retrieval catheter 370 (FIGURES 37-46). According to one embodiment and as shown in FIGURE 25, closure device 250 may include a delivery string 371. As shown in FIGURE 25, delivery string 371 is permanently attached to arc 258a of proximal anchor member 254, although one of skill in the art will recognize that delivery string 371 may be attached anywhere on proximal anchor member 254. Delivery string 371 may be attached in any suitable manner, for example, through a drilled hole, via glue, etc. Delivery string 371 is short (*i.e.*, several millimeters) and as least thrombogenic as possible. As used herein, "string" includes various materials, which may be stiff or flexible. Delivery string 371 terminates in a ball 377 at its free end. Closure device 250 further includes a recovery ball 373 attached to recovery string 374, which is threaded through ends 255 and 257 of proximal anchor member 254 and subsequently attached to end 253 of distal anchor member 252. Slack 375 exists in recovery string 374 between end 253 of distal anchor member 252 and end 257 of proximal anchor member 254. Closure device 250 still further includes a ball 372 attached to recovery string 374 and contained between ends 255 and 257 of proximal anchor member 254. Ends 255 and 257 of proximal anchor member 254 may have an inner diameter greater than that of ball 372 but are tapered such that the terminal segment of ends 255 and 257 have a diameter smaller than that of ball 372. Thus, the movement of ball 372 is constrained between ends 255 and 257 of proximal anchor member 254.

[0109] Prior to deployment *in vivo*, device 250 must be placed within delivery catheter 370 (FIGURE 37). Device 250 may be loaded into catheter 370 in any manner such that slack 375 is maintained in recovery string 374 between distal anchor member 252 and proximal anchor member 254, as shown in FIGURE 37. For example, device 250 may be manually loaded into catheter 370. One skilled in the art will be capable of identifying suitable methods for loading device 250 into catheter 370.

[0110] One of skill in the art will, of course, recognize that the maximum amount of slack 375 in the recovery string 374 is dependent upon the distance ball 372 may travel between ends 255 and 257 of proximal anchor member 254. Slack 375 increases as ball 372 travels closer toward the terminus of end 257. Thus, the amount of slack 375 may be adjusted by altering the tapering of the internal diameter of ends 255 and 257. Additionally, the slit 480 splitting ends 255 and 257 of proximal anchor member 254 into arcs 258a and 258b may be extended toward the termini of ends 255 and 257 so as to maximize the distance ball 372 may travel within proximal anchor member 254 and, correspondingly, the slack 375 (FIGURE 47).

[0111] Device 250 may be delivered to its intended delivery site *in vivo* by various methods, only one of which will be described herein. As shown in FIGURE 38, the clinician holds both recovery ball 373 and delivery ball 377 by suitable devices, *e.g.*, grips 376 and 401. As used herein, the terms "ball" and "grips" are used to generically describe the delivery mechanism. One skilled in the art will recognize that the precise structure of the delivery mechanism components may vary. Grips 376 and 401 permit the clinician to apply tension or compression to delivery string 371 or recovery string 374 as desired to properly manipulate device 250. Generally, during delivery of device 250 by the method described herein, tension will be applied only to delivery string 371; recovery string 374 will be held in a relaxed configuration such that slack 375 is maintained. Once the clinician is properly holding both recovery ball 373 and delivery ball 377, catheter 370 is delivered through the patient's vasculature to the right atrium 10 of the heart (FIGURE 38). Then, as shown in FIGURE 39, catheter 370 is inserted between septum primum 14 and septum secundum 16 into the left atrium 12. Distal anchor member 252 is ejected into the left atrium 12 by pushing on grips 401, and arcs 256a and 256b reassume their elongate oval configuration

(FIGURE 39). Catheter 370 is withdrawn between septum primum 14 and septum secundum 16 and into the right atrium 10, such that proximal anchor member 254 is deployed into the right atrium 10 and slack 375 extends through the PFO (FIGURE 40). During this process, grips 401 are maintained on delivery ball 377, and the necessary tension is applied to delivery string 371 (FIGURE 40). As shown in FIGURE 40, arcs 258a and 258b reassume their elongate oval configuration upon deployment of proximal anchor member 254 into the right atrium 10, and proximal anchor member 254 may be positioned as desired against the septal tissue using grips 401. Distal anchor member 252 and proximal anchor member 254 cooperate to apply a compressive force to septum primum 14 and septum secundum 16, thereby closing the PFO (FIGURE 41). If deployment of closure device 250 is satisfactory to the clinician, grips 401 release delivery ball 377, grips 376 release recovery ball 373 (FIGURE 41), and catheter 370 is withdrawn from the right atrium 10 and further withdrawn through the patient's vasculature.

[0112] However, if, following deployment, the clinician is not satisfied with the position of device 250, grips 376 and grips 401 may be maintained on balls 373 and 377, respectively, so that the device 250 may be repositioned and/or retrieved. Device 250 may be repositioned by further manipulating the tension applied to delivery string 371 by grips 401 (FIGURE 42). To retrieve closure device 250, catheter 370 is positioned against end 255 (FIGURE 43). Recovery ball 373 is pulled into the catheter 370, such that ball 372 moves to point B of end 255 and arcs 258a and 258b of proximal anchor member 254 are collapsed and withdrawn into catheter 360 (FIGURE 44). Upon nearing complete retrieval of proximal anchor member 254, slack 375 in string 374 is eliminated, or nearly so, and end 257 of proximal anchor member 254 and end 253 of distal anchor member 252 are touching, or nearly touching, such that proximal anchor member 254 and distal anchor member 252 are aligned in a longitudinal, end-to-end manner (FIGURE 44). Grips 376 continue to apply tension to recovery string 374, pulling recovery ball 373 toward the proximal end of catheter 370, as shown in FIGURE 45. Arcs 256a and 256b of distal anchor member 252 are collapsed, and distal anchor member 252 is withdrawn into catheter 370 (FIGURE 45). Catheter 370 is then withdrawn through the PFO, and into the right atrium 10 (FIGURE 46).

[0113] The delivery and recovery system of device 250 may be modified in various ways, one of which is shown in the device 490 of FIGURES 50-51. String 374 may be extended from end 255 of proximal anchor member 254 toward arc 258a, be attached to arc 258 at a point Y, further extend from arc 258a to form delivery/recovery string 491, and terminate in delivery/recovery ball 492 (FIGURE 50). The device 490 may be deployed as described above, except that only grips 401 would be necessary hold delivery/recovery ball 492 and manipulate the tension applied to delivery/recovery string 491 during delivery. To retrieve device 490, grips 401 apply sufficient tension to delivery/recovery string 491 to break its connection to arc 258a of proximal anchor member 254 at point Y (FIGURE 50). By applying further tension to delivery/recovery string 374 by pulling delivery/recovery ball 492 towards the proximal end of the catheter 370, device 490 orients in a longitudinal manner and may be withdrawn into the catheter 370 as described previously.

[0114] The closure devices described herein can optionally be used along with suturing or stapling techniques where the anchors or flexible joints of the devices can be sewn or stapled to septum primum 14 and/or septum secundum 16 for better dislodgment resistance. Also, the flexible joint can, if desired, be covered with a biocompatible adhesive to adhere to the tissue or can be loaded with drugs or growth factors to promote healing. The adhesive and also certain drugs can also optionally be stored in any cavities in the anchor members 252 and/or 254 (*e.g.*, in the cylindrical members of FIGURES 6 and 7) and released after deployment. Radiopaque markers can also be attached to the closure devices for better visualization during the implantation procedure. One skilled in the art will recognize that a variety of visualization techniques may be used, including fluoroscopy and magnetic resonance imaging (MRI).

[0115] The various closure devices described herein may further include a number of advantageous features. The closure devices preferably have an atraumatic shape to reduce trauma during deployment or removal. In addition, the devices can be self-orienting for ease of deployment. Furthermore, because of the flexible center joint, the devices generally conform to the anatomy instead of the anatomy conforming to the devices, which is especially useful in long tunnel defects. In addition, the devices can preferably be repositioned and/or removed during delivery. The devices

also generally have a relatively low profile after deployment. The flexible center joint 259 of the devices can encourage faster tissue ingrowth and therefore, faster defect closure. Furthermore, there are generally no exposed thrombogenic components in the left 12 and right 10 atria. Still further, the devices may advantageously include bioresorbable components, which will disappear from the body over time.

[0116] One skilled in the art will recognize that the features of any embodiment described herein may be combined with those of any other embodiment described herein.

[0117] Other benefits of the devices described herein include the possible use of a relatively small diameter delivery sheath, use of a reduced amount, or no, metal mass in the device, ease of manufacturing, cost effectiveness, and overall design simplicity.

[0118] Having described preferred embodiments of the present invention, it should be apparent that various modifications may be made without departing from the spirit and scope of the invention, which is defined in the claims below.

What is claimed is:

1. A device for closing a defect in septal tissue, comprising:

a first side adapted to be disposed on one side of the septal tissue and a second side adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by at least one center joint,

wherein each of said first and second sides includes an anchor member, and

wherein the anchor member of at least one of said first and second sides comprises a generally cylindrical member split along the central portion of its length to form an elongate oval.

2. The device of Claim 1, wherein said at least one center joint extends through the defect in the septal tissue when said device is deployed at its intended delivery location.

3. The device of Claim 2, wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect.

4. The device of Claim 1, wherein each of said first and second sides comprises a generally cylindrical member split along the central portion of its length to form an elongate oval.

5. The device of Claim 4, wherein said first and second anchor members are three- dimensional.

6. The device of Claim 1, wherein said anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials.

7. The device of Claim 1, wherein said at least one center joint includes a stretchable elastomeric material.

8. The device of Claim 7, wherein said at least one center joint includes a shape memory material.

9. The device of Claim 8, wherein said at least one center joint includes nitinol.

10. The device of Claim 9, wherein said at least one center joint comprises a nitinol film.

11. The device of Claim 10, wherein said nitinol film includes openings selected from the group consisting of slits and holes.

12. The device of Claim 7, wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue.

13. The device of Claim 12, wherein said at least one center joint includes a material selected from the group consisting of thrombogenic materials, inflammatory materials, drug-exuding materials, and combinations of the foregoing materials.

14. The device of Claim 7, wherein said at least one center joint is porous.

15. The device of Claim 1, wherein at least one of said first and second anchor members includes a tissue scaffold.

16. The device of Claim 15, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials.

17. The device of Claim 15, wherein each of said first and second anchor members includes a tissue scaffold.

18. The device of Claim 17, wherein said at least one center joint is connected to said tissue scaffolds.

19. The device of Claim 1, wherein said device is retrievable.

20. A device for closing a defect in septal tissue, comprising:

a first side adapted to be disposed on one side of the septal tissue and a second side adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by a at least one center joint,

wherein each of said first and second sides includes an anchor member comprising a generally cylindrical member split along the central portion of its length to form an elongate oval, and

wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect when said device is deployed at an intended delivery location.

21. The device of Claim 20, wherein said anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials.

22. The device of Claim 21, wherein each of said elongate oval anchor members is three-dimensional.

23. The device of Claim 22, wherein each of said elongate oval anchor members is configured to minimize the septal profile of said device.

24. The device of Claim 23, wherein the arcs of said elongate oval anchor members are positioned at an angle θ from the plane of said device.

25. The device of claim 24, wherein each of said elongate oval anchor members is concave in shape.

26. The device of Claim 24, wherein said angle θ is greater than 0 degrees and less than about 45 degrees.

27. The device of Claim 20, wherein each of said first and second anchor members includes a tissue scaffold.

28. The device of Claim 27, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials.

29. The device of Claim 20, wherein said at least one center joint includes a stretchable elastomeric material.

30. The device of Claim 29, wherein said at least one center joint includes a shape memory material.

31. The device of Claim 30, wherein said at least one center joint includes nitinol.

32. The device of Claim 29, wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue.

33. The device of Claim 32, wherein said at least one center joint includes a material selected from the group consisting of thrombogenic materials, inflammatory materials, drug-exuding materials, and combinations of the foregoing materials.

34. The device of Claim 20, further comprising a retrieval mechanism for retrieving said device from its intended delivery location.

35. The device of Claim 34, wherein said retrieval mechanism reduces the profile of said device such that said device may drawn into a catheter.

36. The device of Claim 35, wherein said retrieval mechanism reduces the distance between said first and second anchor members and aligns said first and second anchor members in a longitudinal orientation.

37. The device of Claim 35, wherein said retrieval mechanism comprises

a string extending from one end of said first anchor member to and through said second anchor member, and

a ball constrained on said string within said second anchor member.

38. The device of Claim 37, wherein said string is flexible.

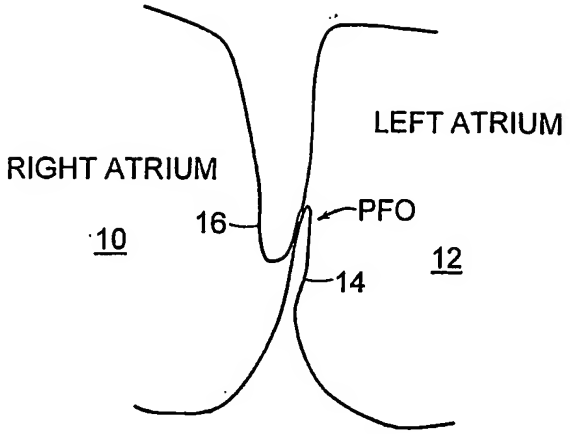

FIG. 1

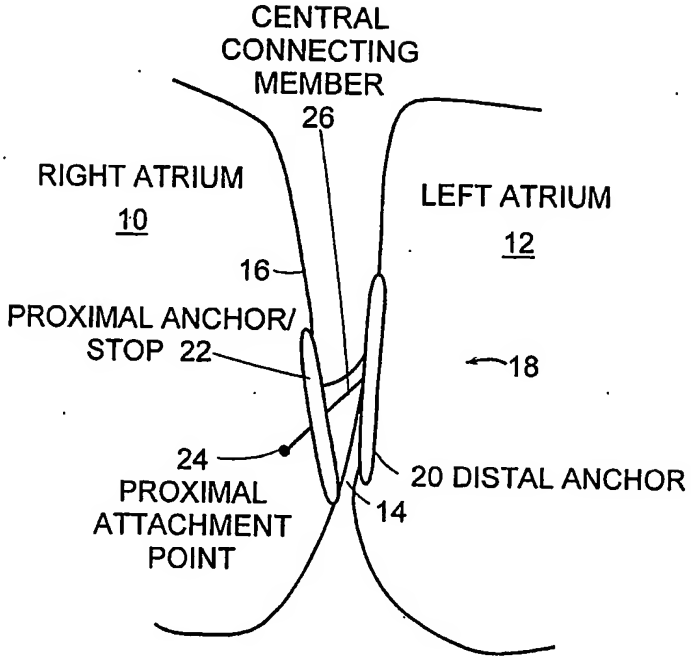

FIG. 2

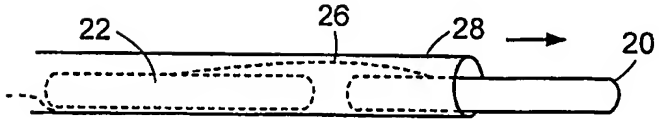

FIG. 3

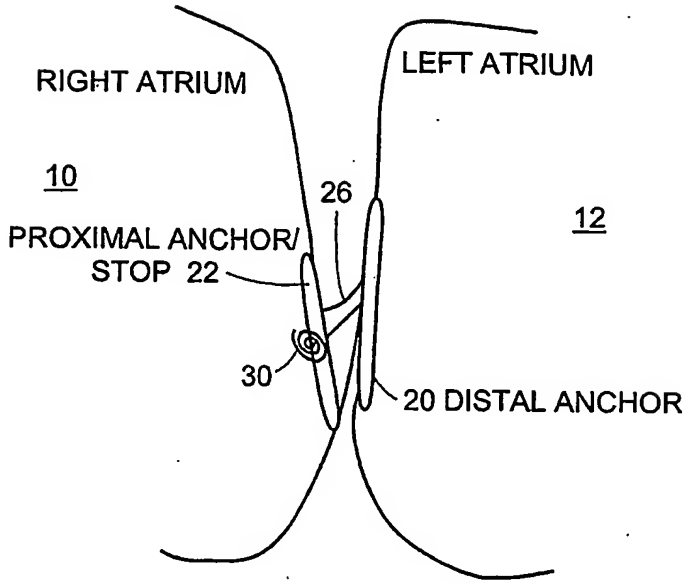
RIGHT ATRIUM
LEFT ATRIUM
10
26
12
PROXIMAL ANCHOR/
STOP 22
30
20 DISTAL ANCHOR

FIG. 4

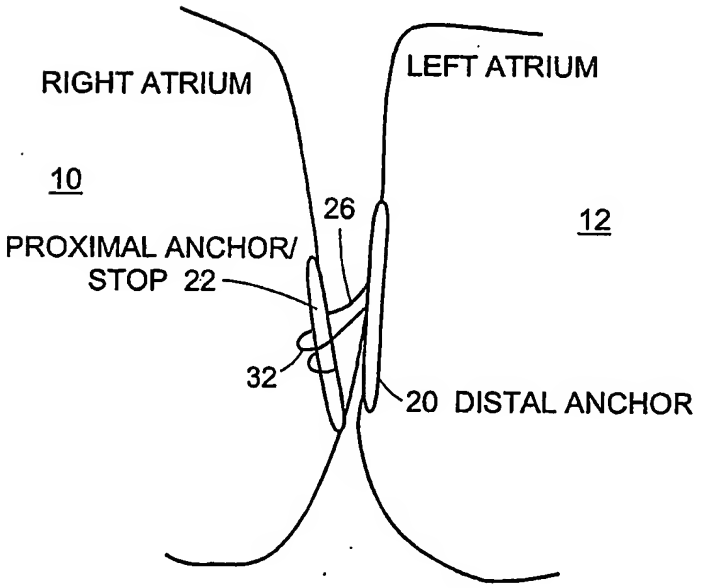
RIGHT ATRIUM
LEFT ATRIUM
10
26
12
PROXIMAL ANCHOR/
STOP 22
32
20 DISTAL ANCHOR

FIG. 5

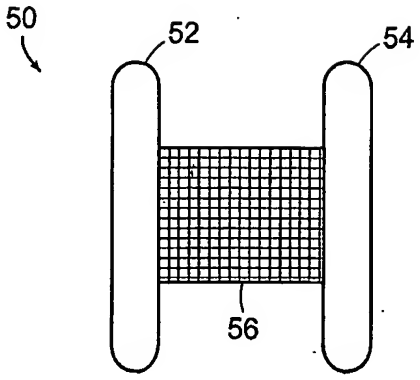

FIG. 6A

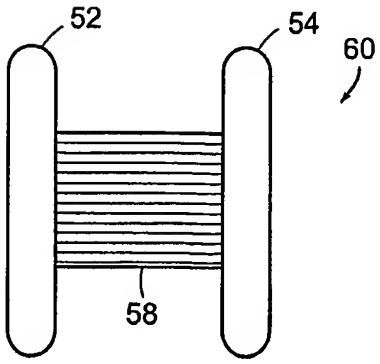

FIG. 7A

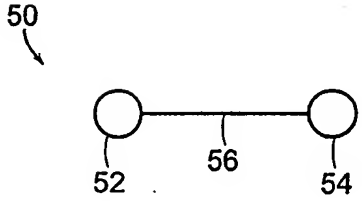

FIG. 6B

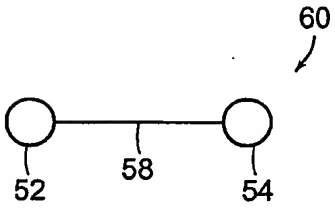

FIG. 7B

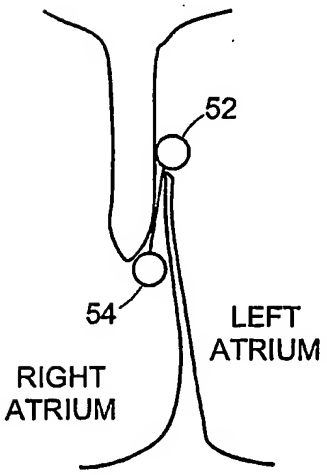

FIG. 8A

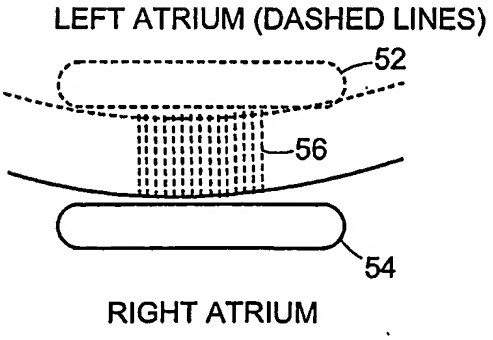

FIG. 8B

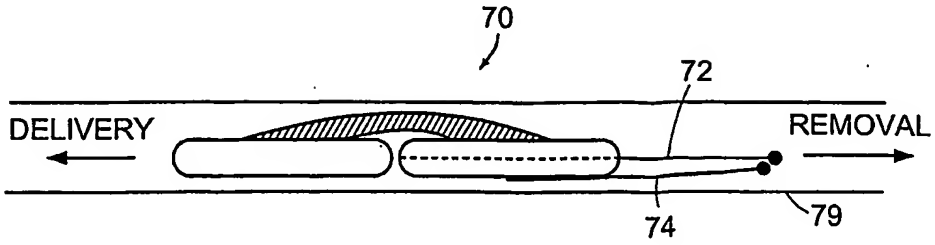

FIG. 9A

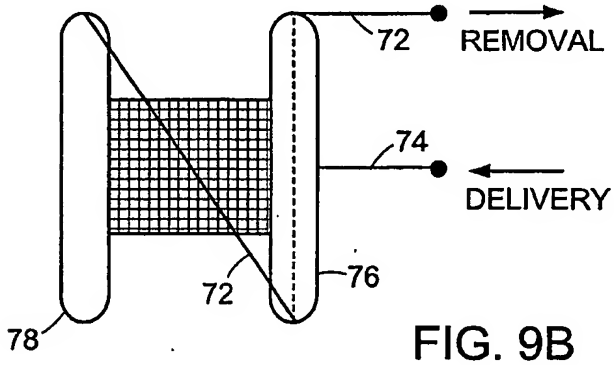

FIG. 9B

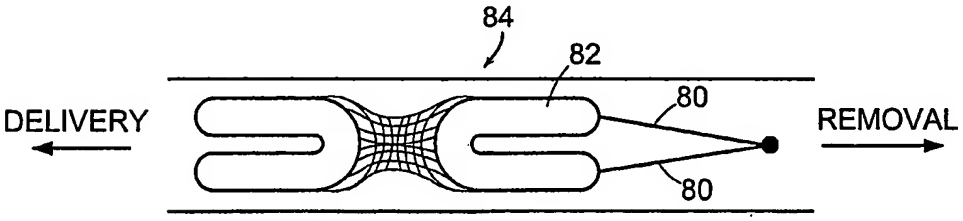

FIG. 10A

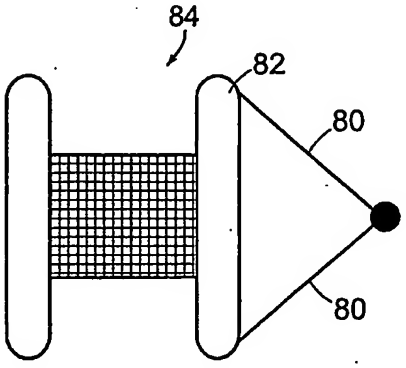

FIG. 10B

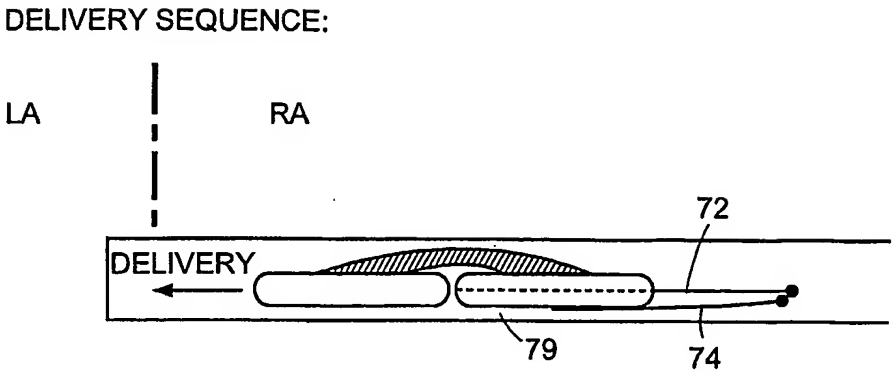

FIG. 9C

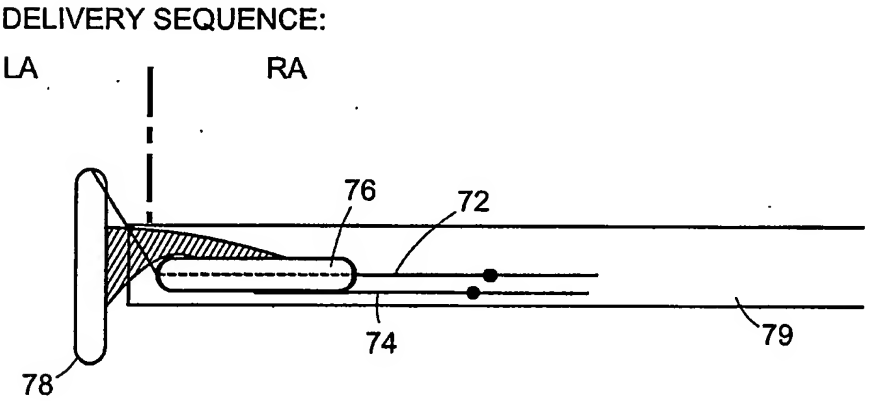

FIG. 9D

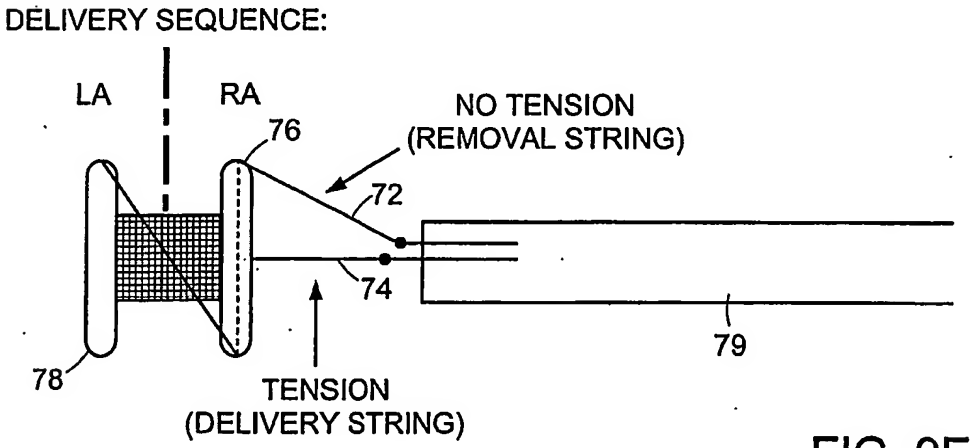

FIG. 9E

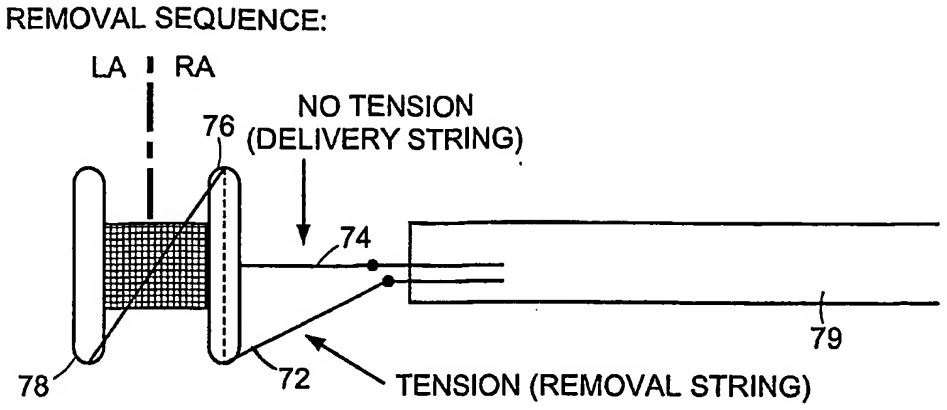

FIG. 9F

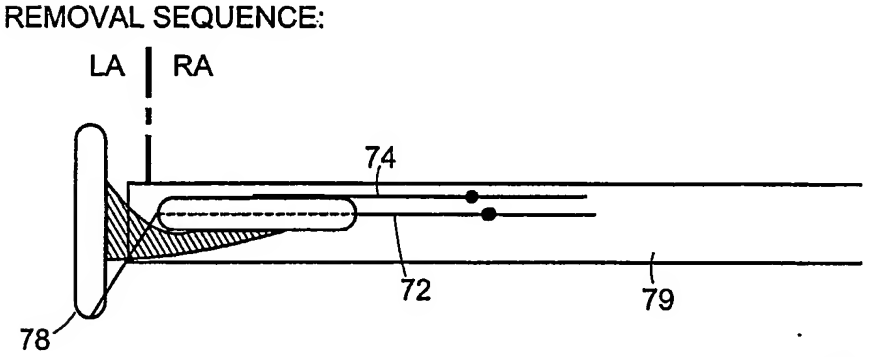

FIG. 9G

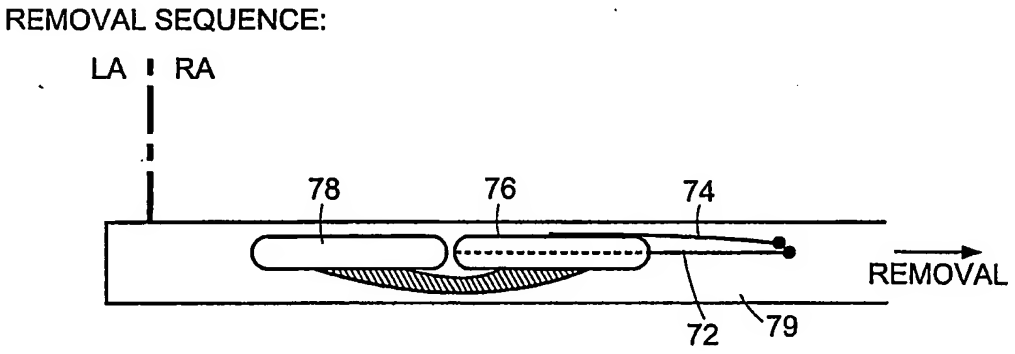

FIG. 9H

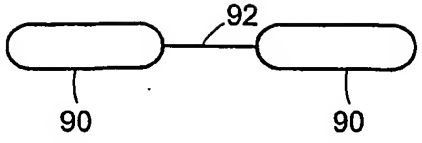

FIG. 11A

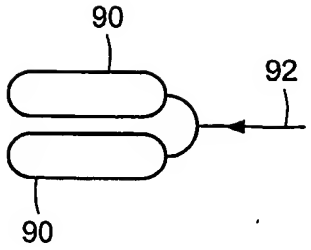

FIG. 11B

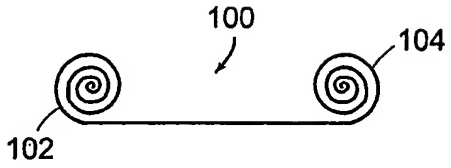

FIG. 12

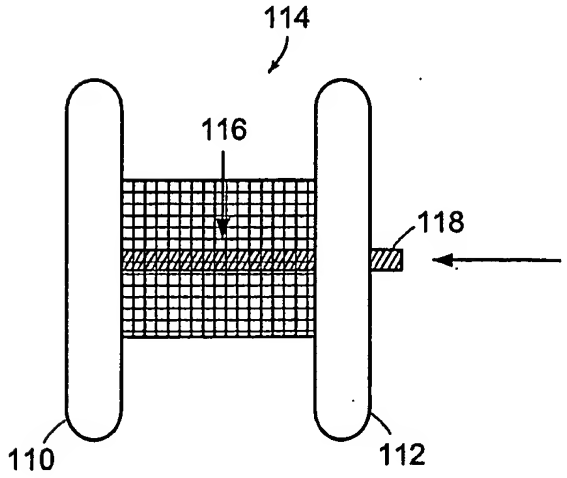

FIG. 13

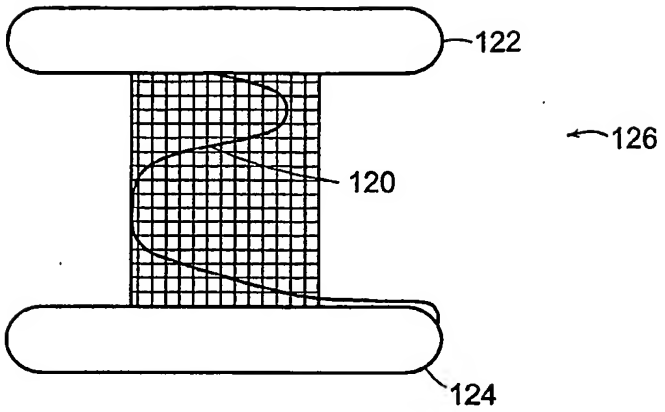

FIG. 14

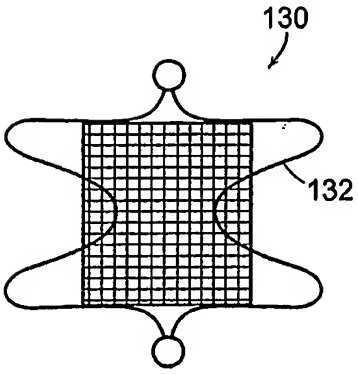

FIG. 15

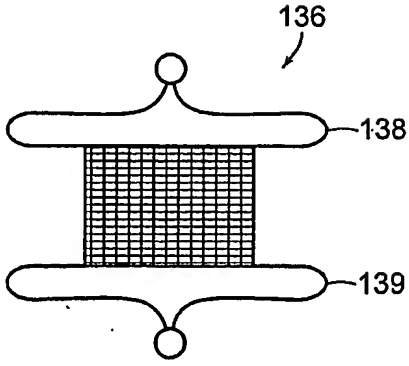

FIG. 16

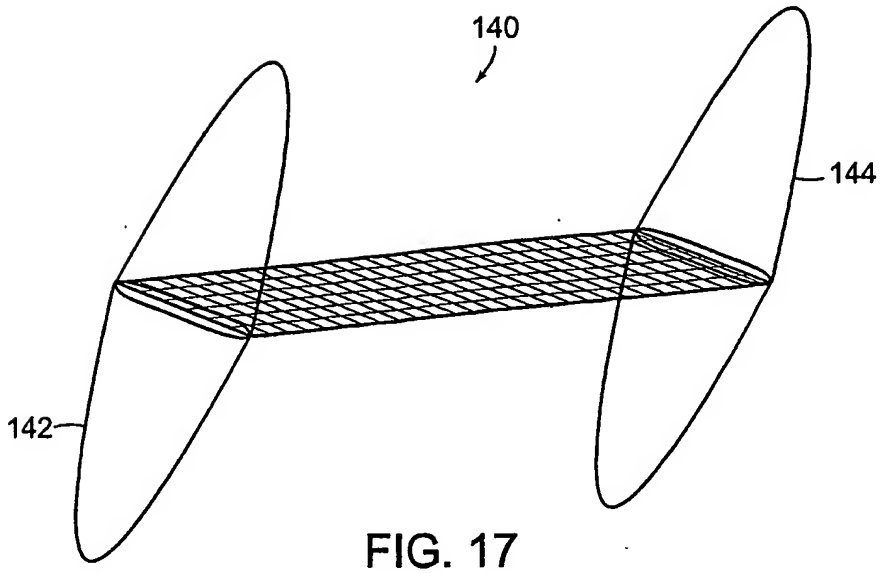

FIG. 17

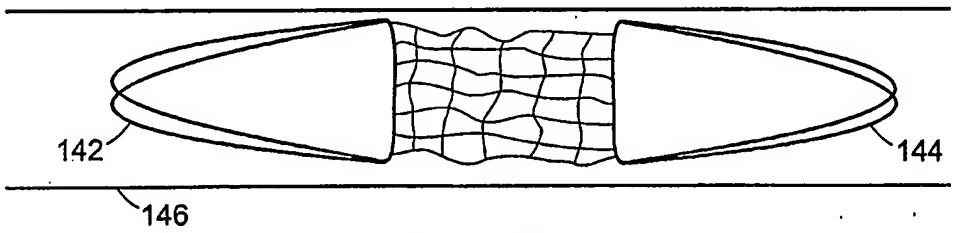

FIG. 18

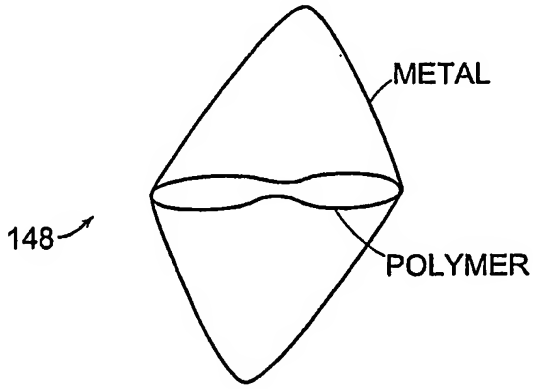

FIG. 19

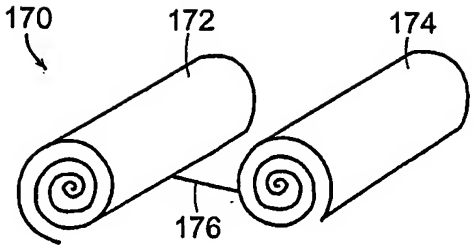

FIG. 20A

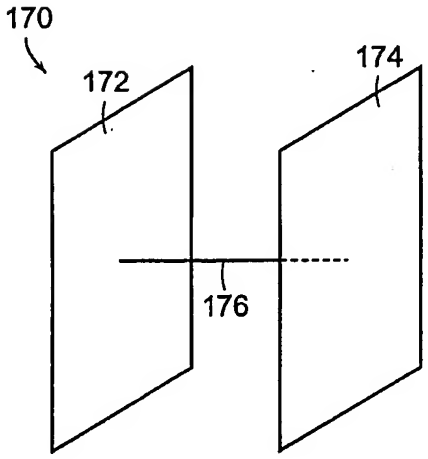

FIG. 20B

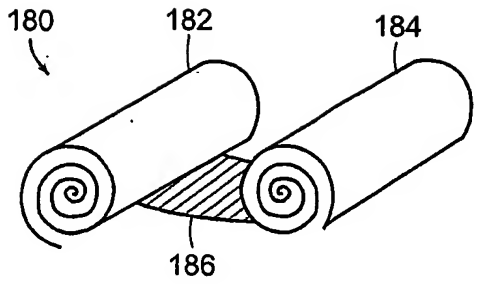

FIG. 21A

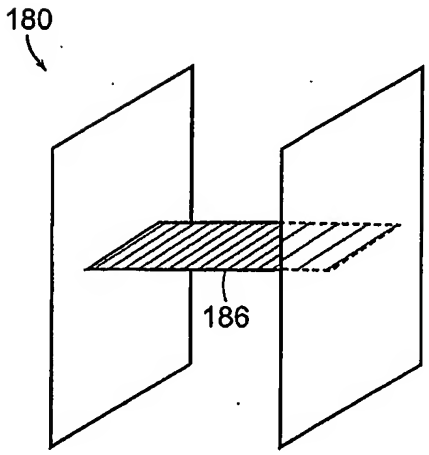

FIG. 21B

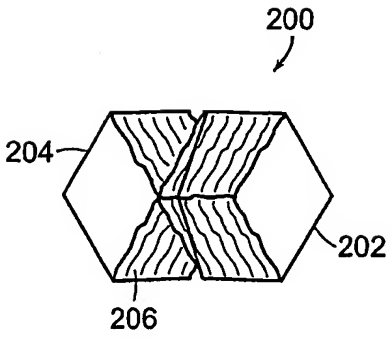

FIG. 22A

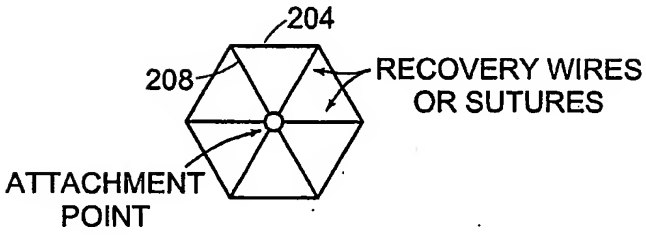

FIG. 22B

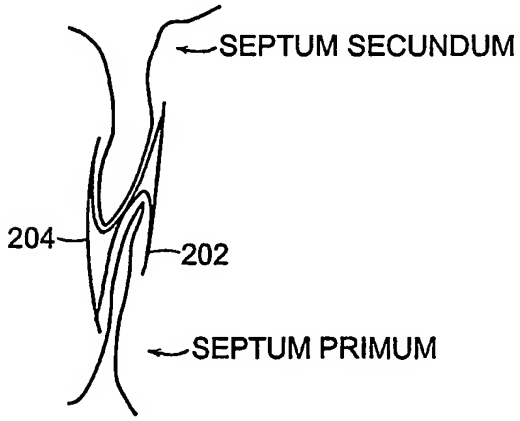

FIG. 22C

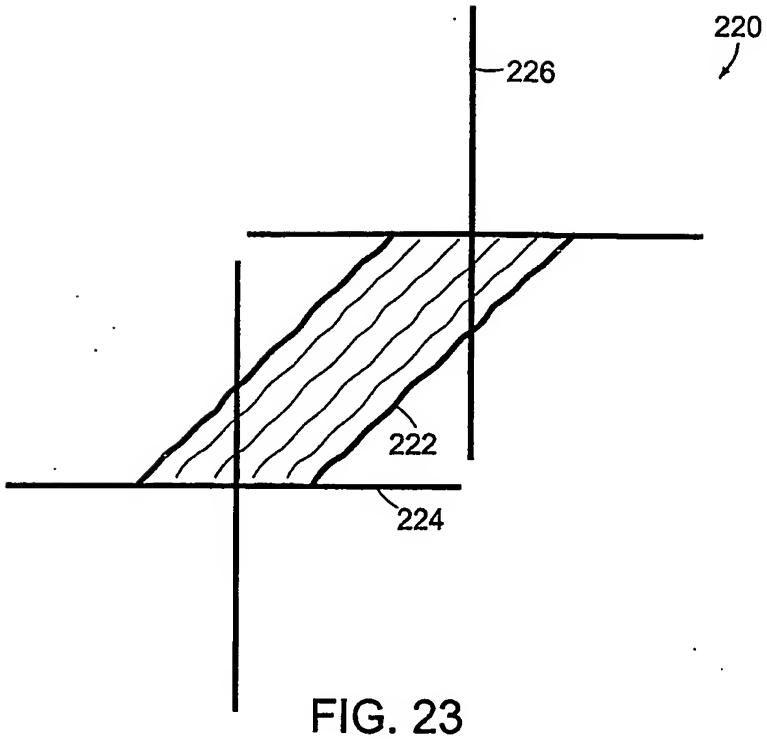

FIG. 23

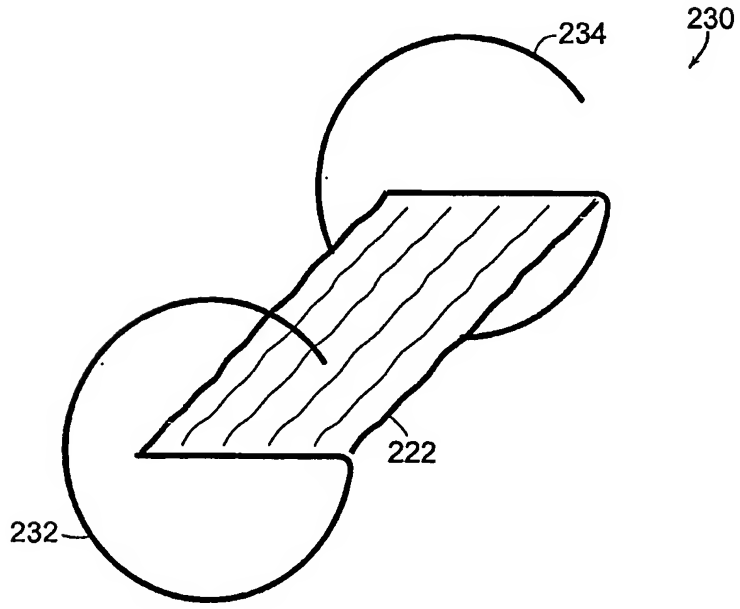

FIG. 24

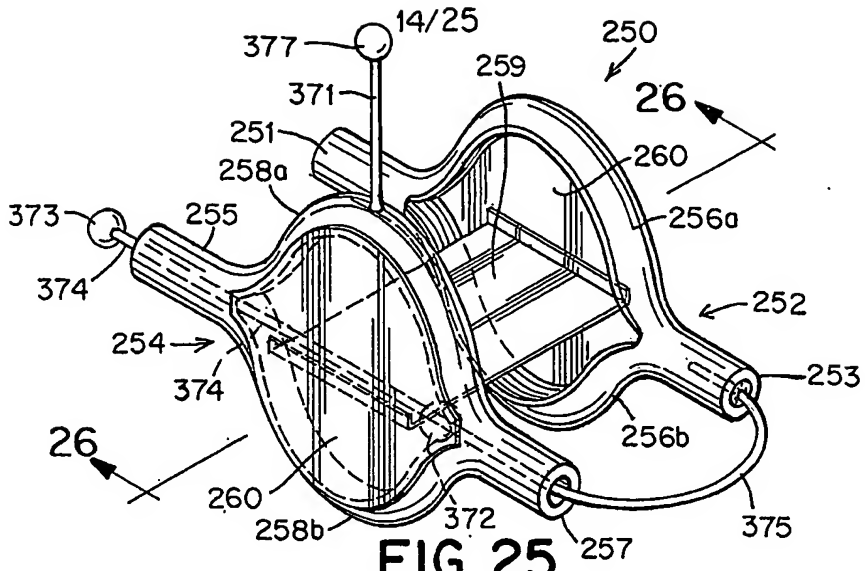

FIG. 25

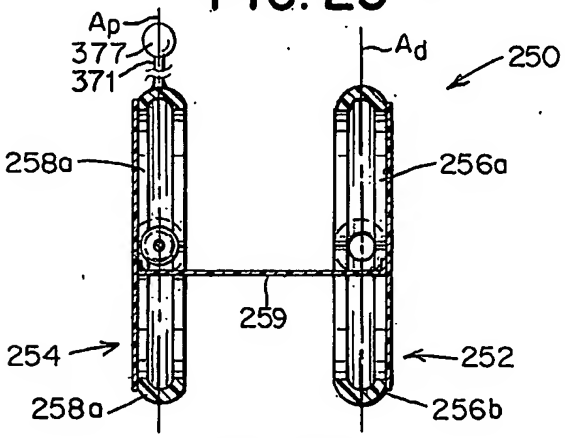

FIG. 26

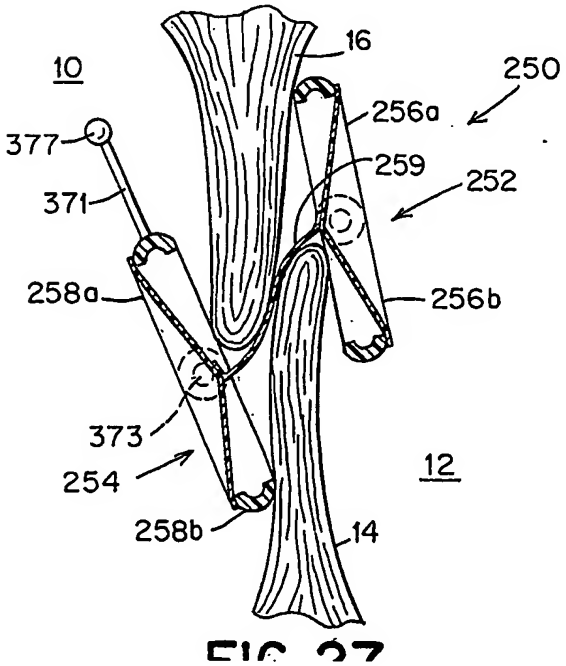

FIG. 27

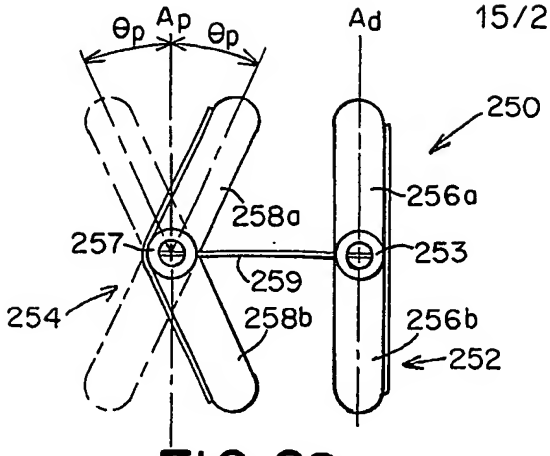

FIG. 28

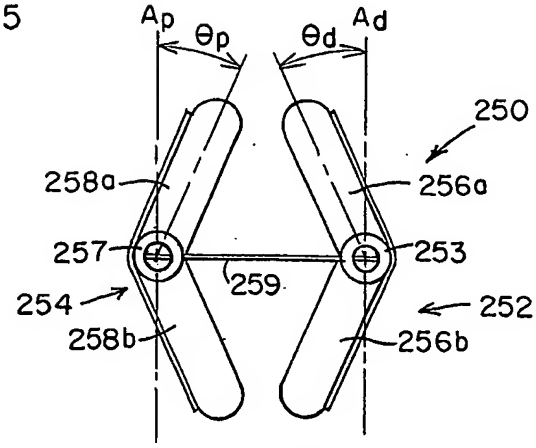

FIG. 29

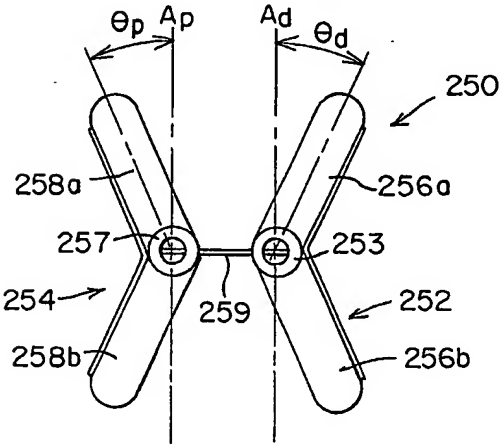

FIG. 30

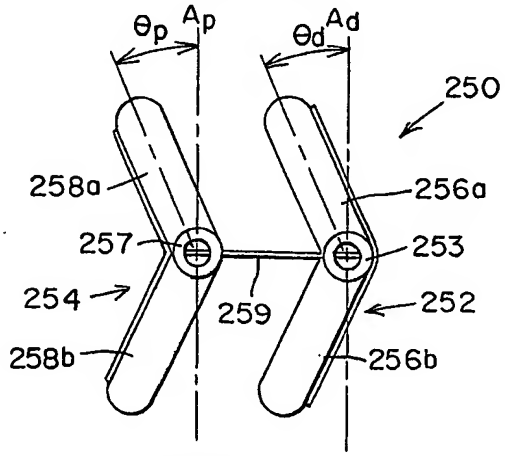

FIG. 31

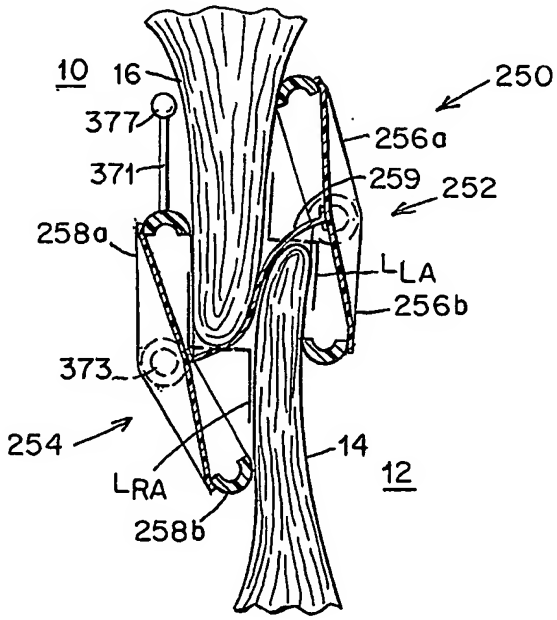

FIG. 32

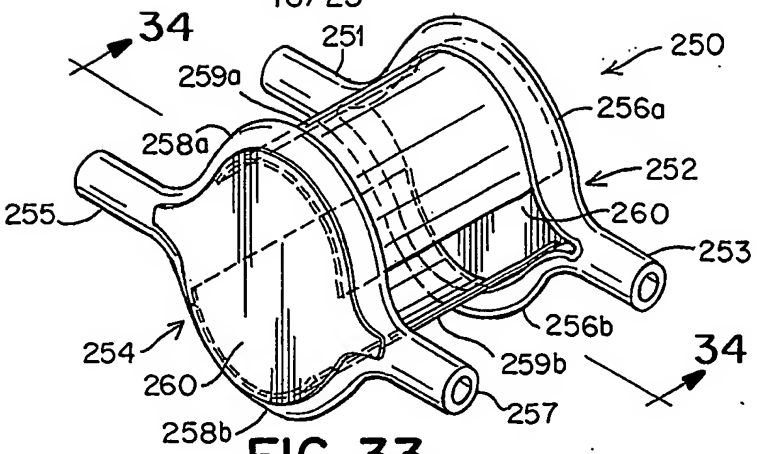

FIG. 33

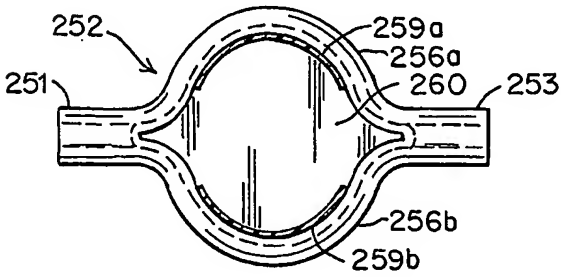

FIG. 34

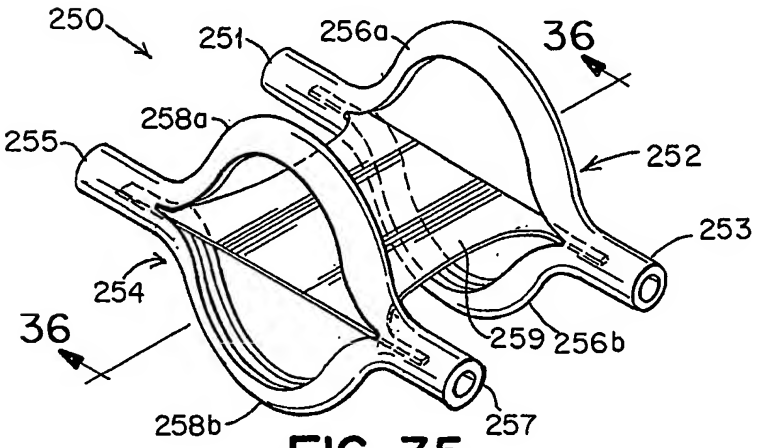

FIG. 35

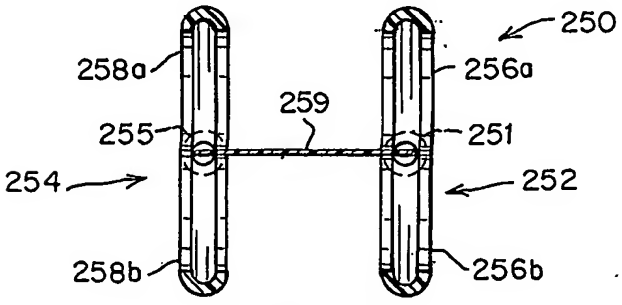

FIG. 36

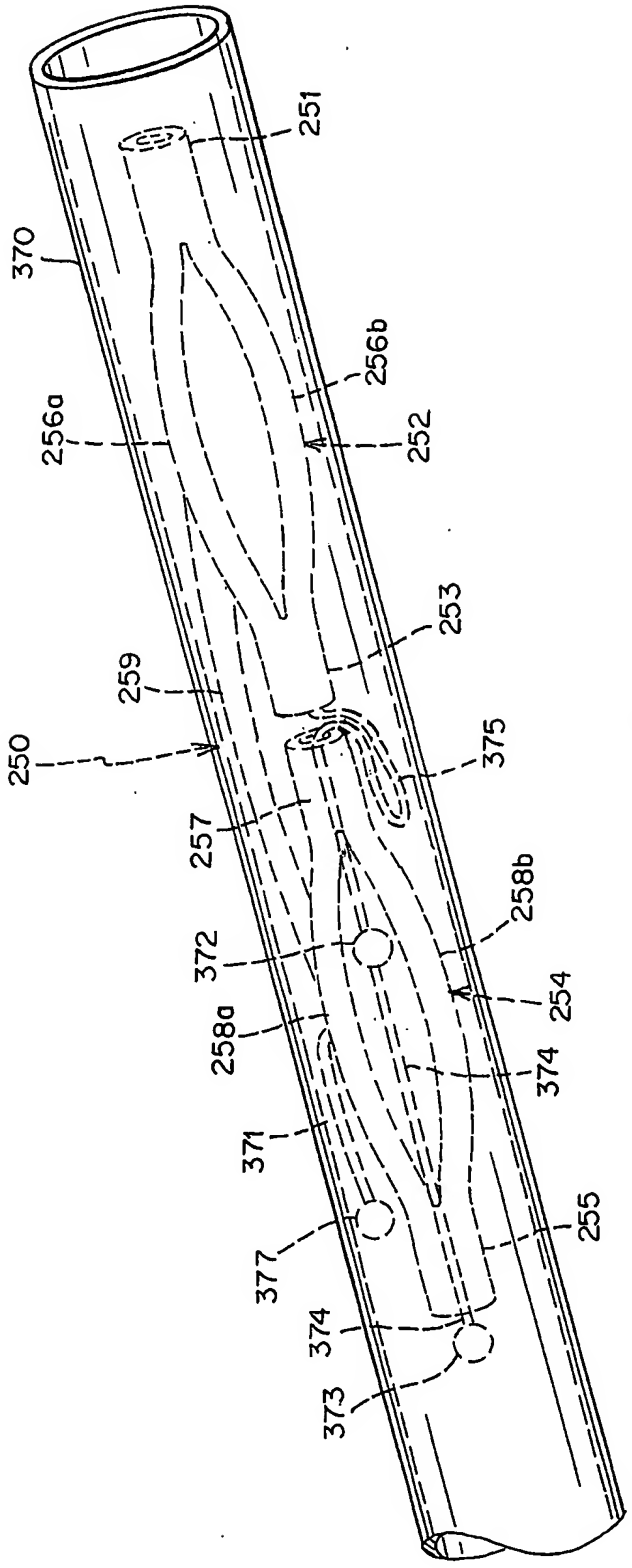
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FIG. 37

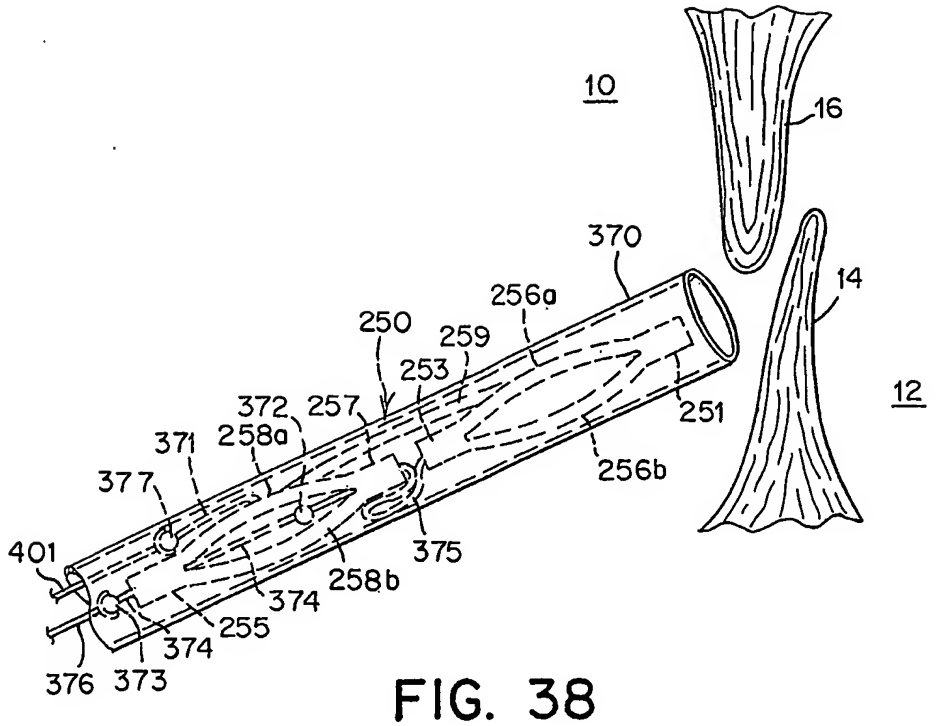
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FIG. 38

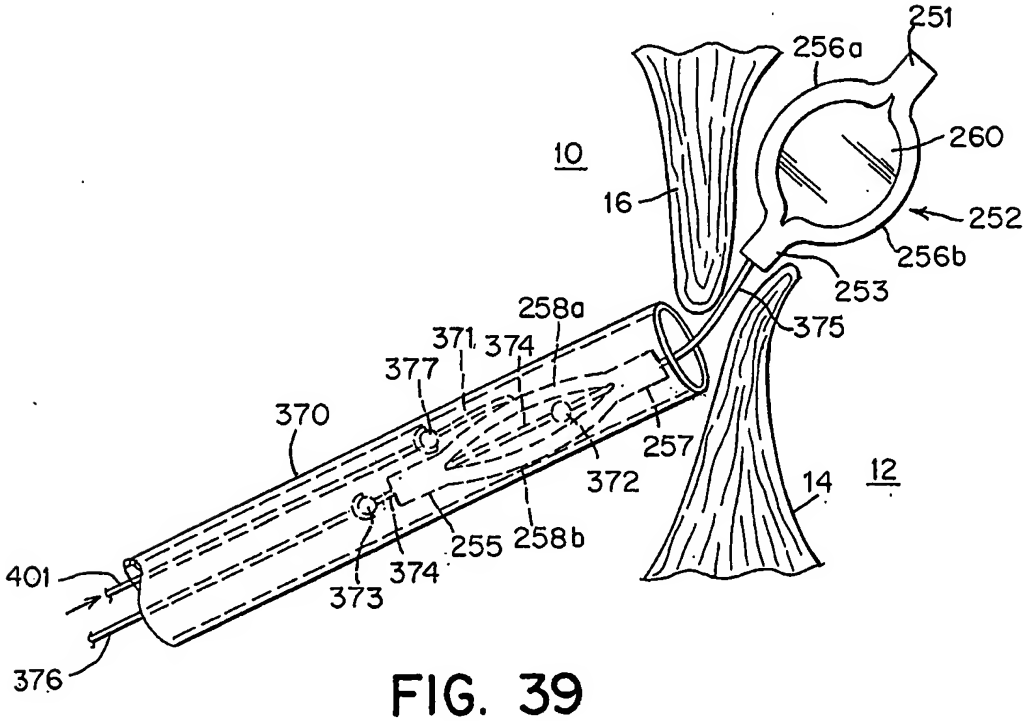
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FIG. 39

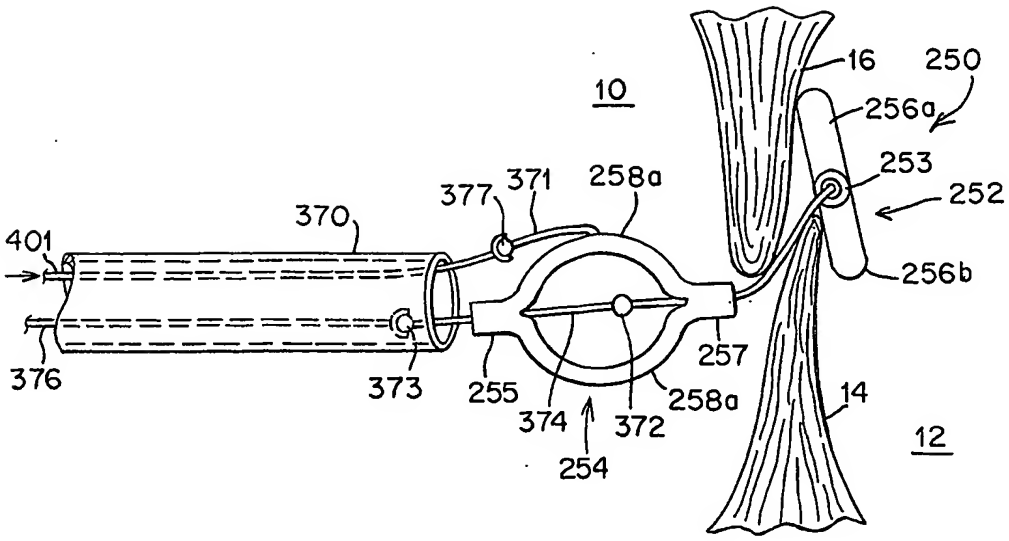
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FIG. 40

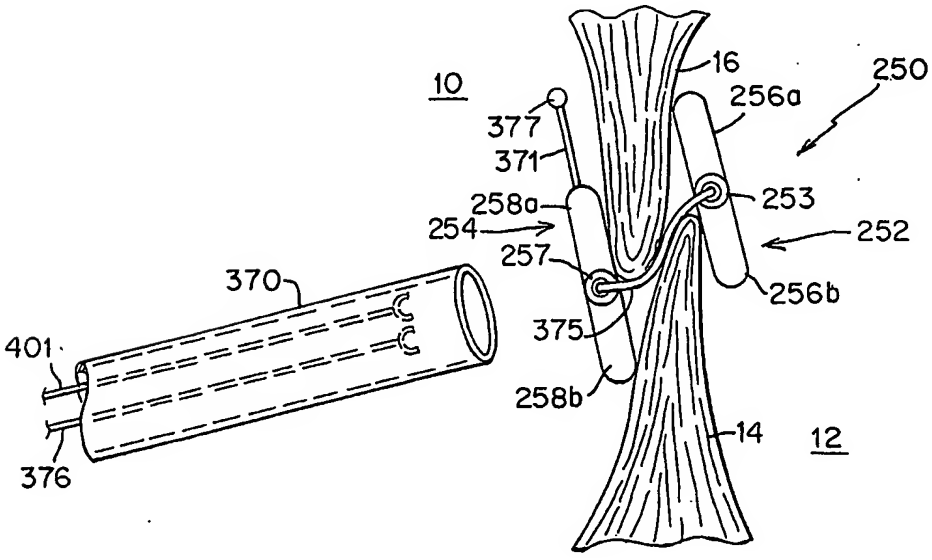
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FIG. 41

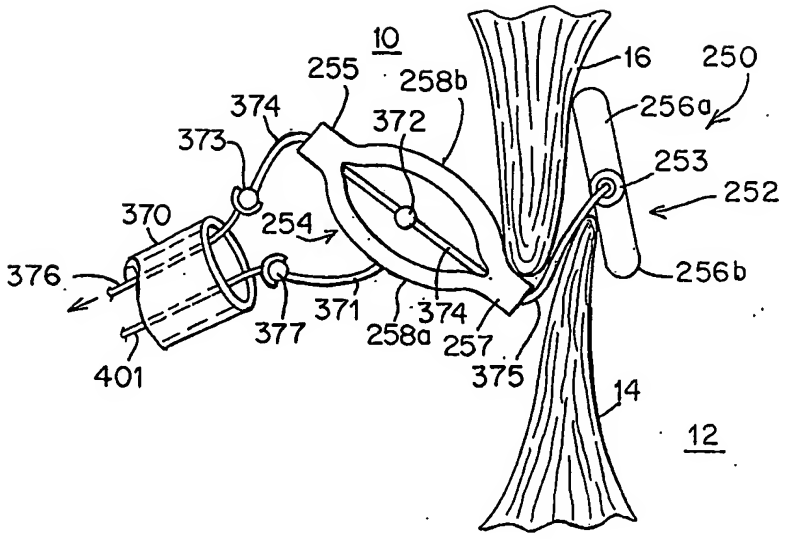
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FIG. 42

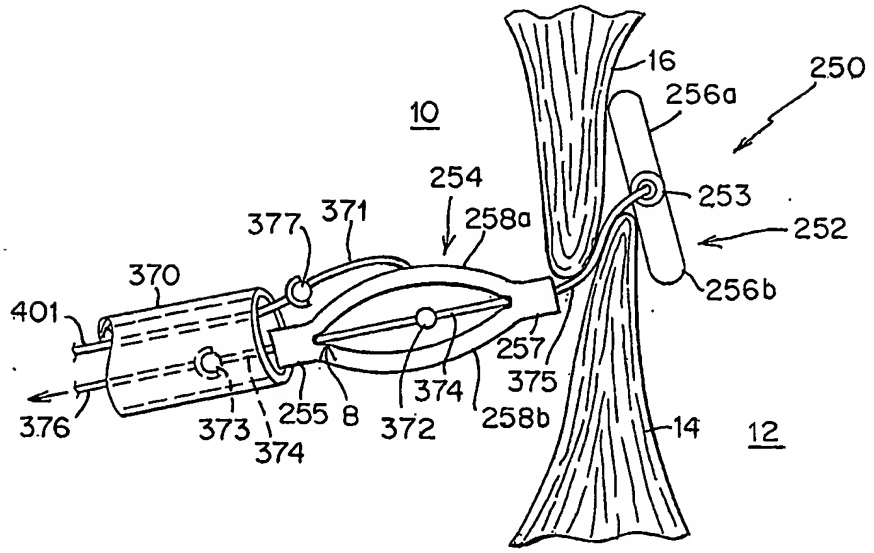
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FIG. 43

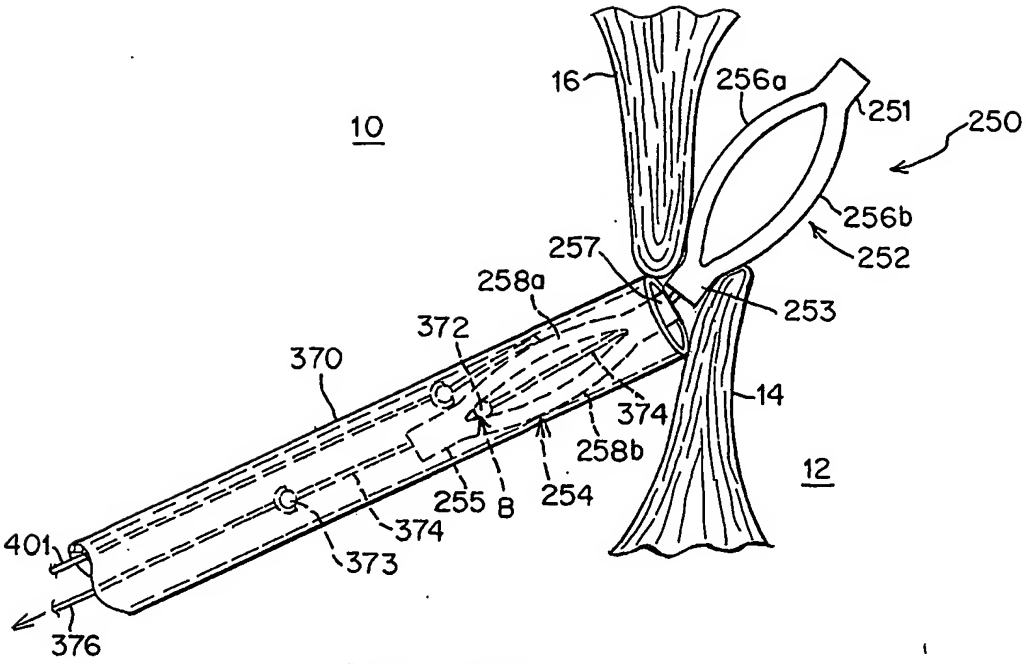
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FIG. 44

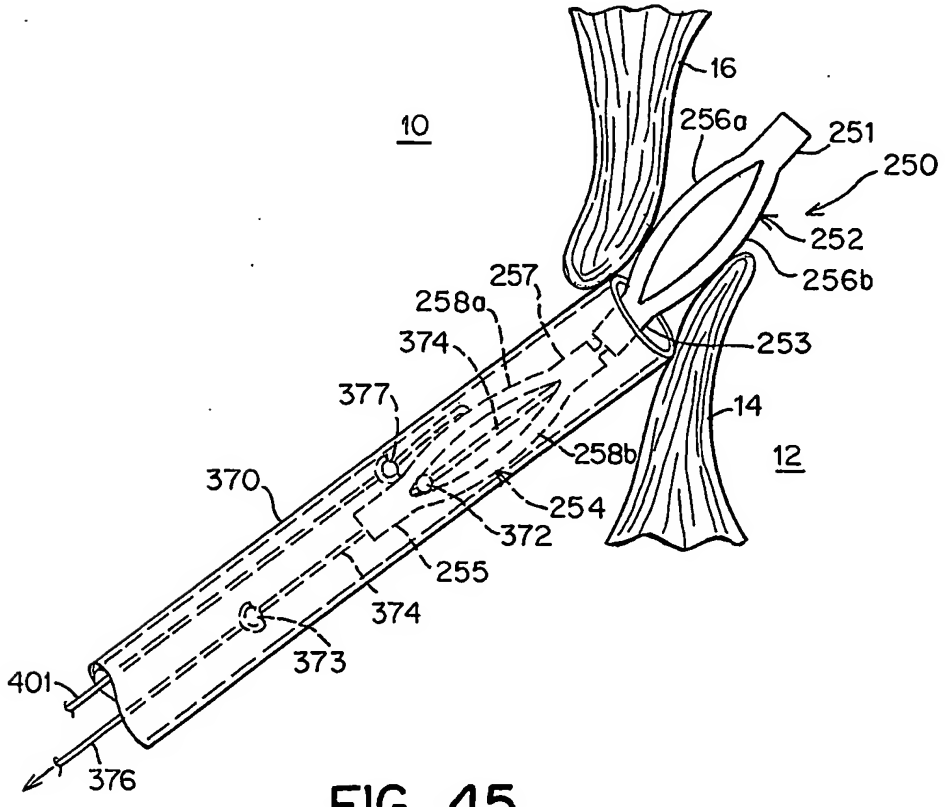
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FIG. 45

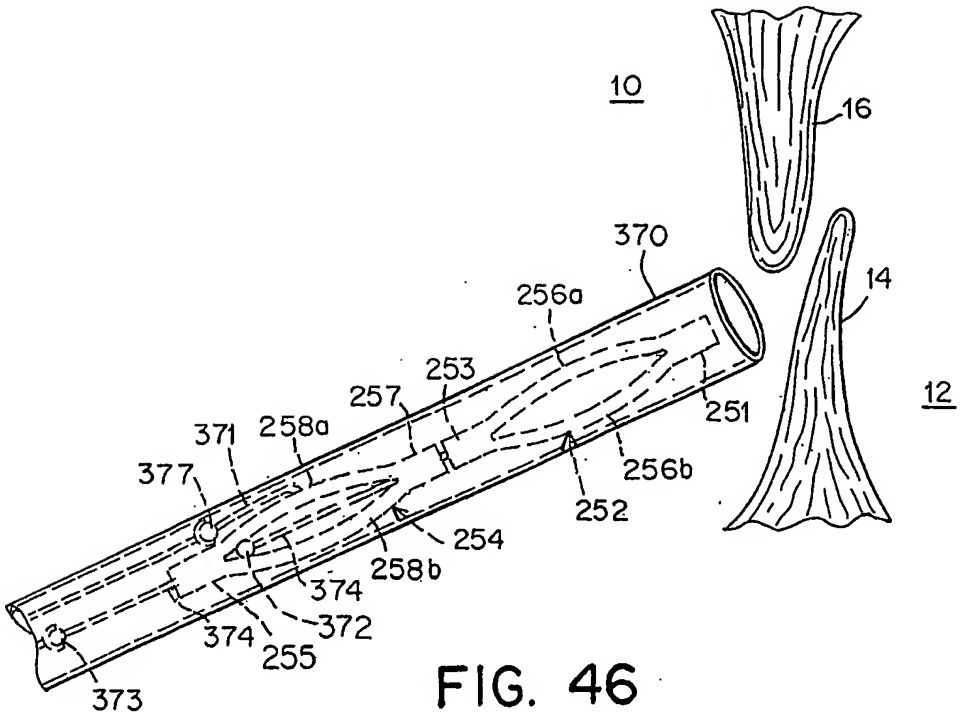
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FIG. 46

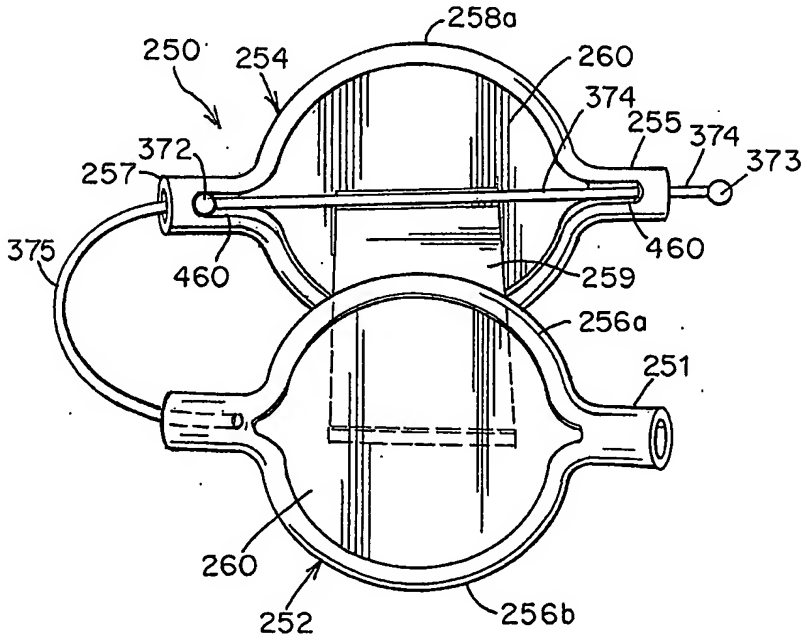
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FIG. 47

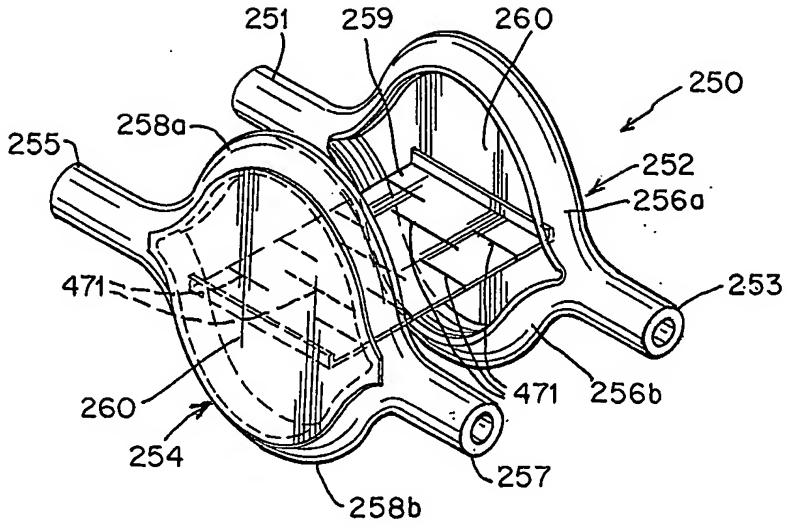

FIG. 48A

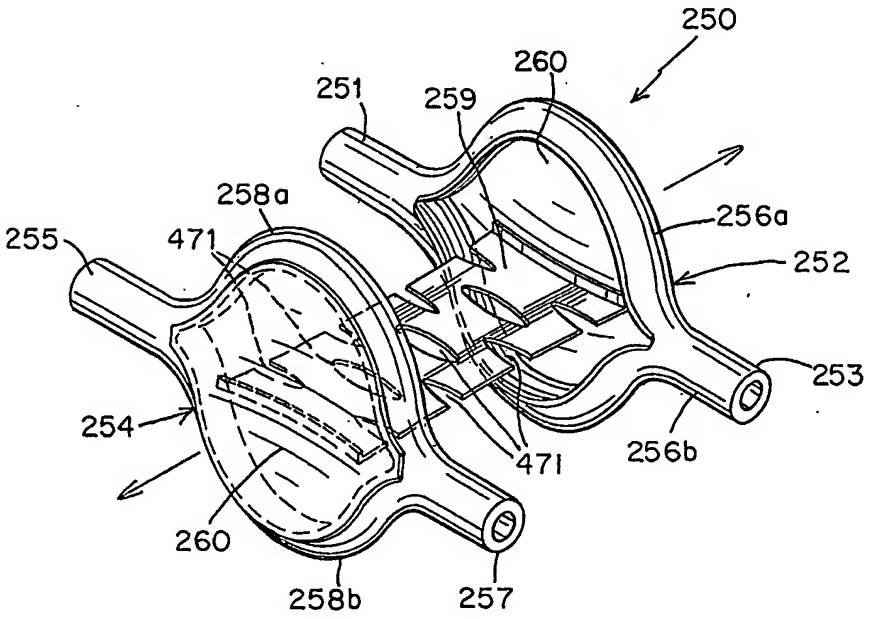

FIG. 48B

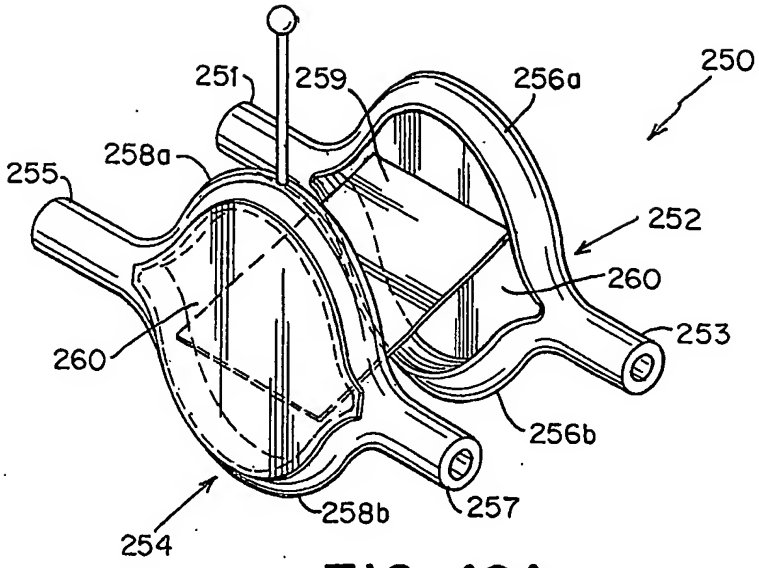

FIG. 49A

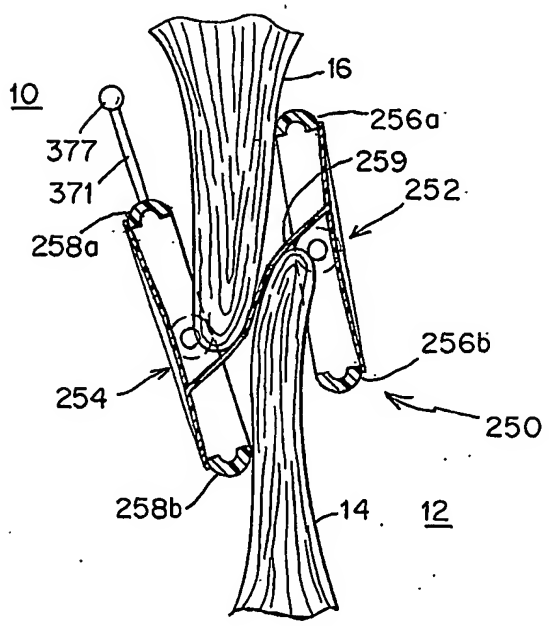

FIG. 49B

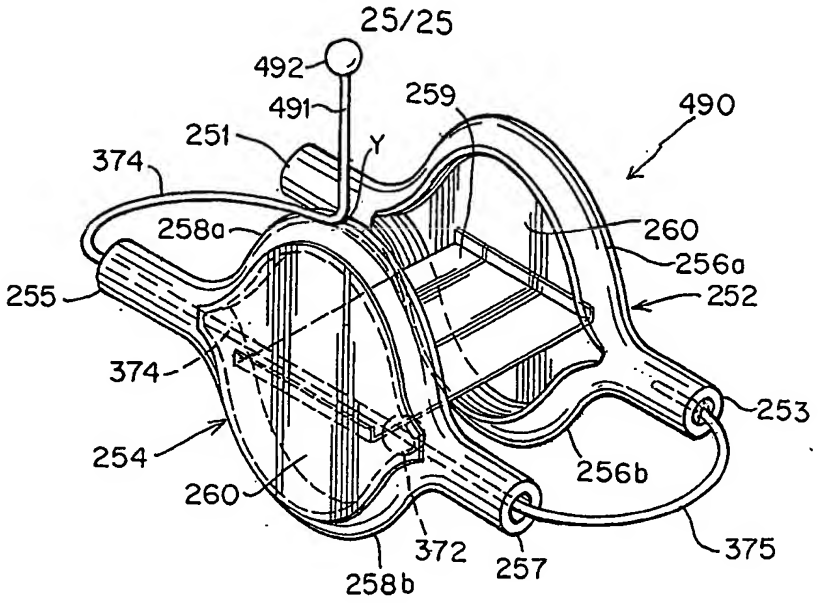
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FIG. 50

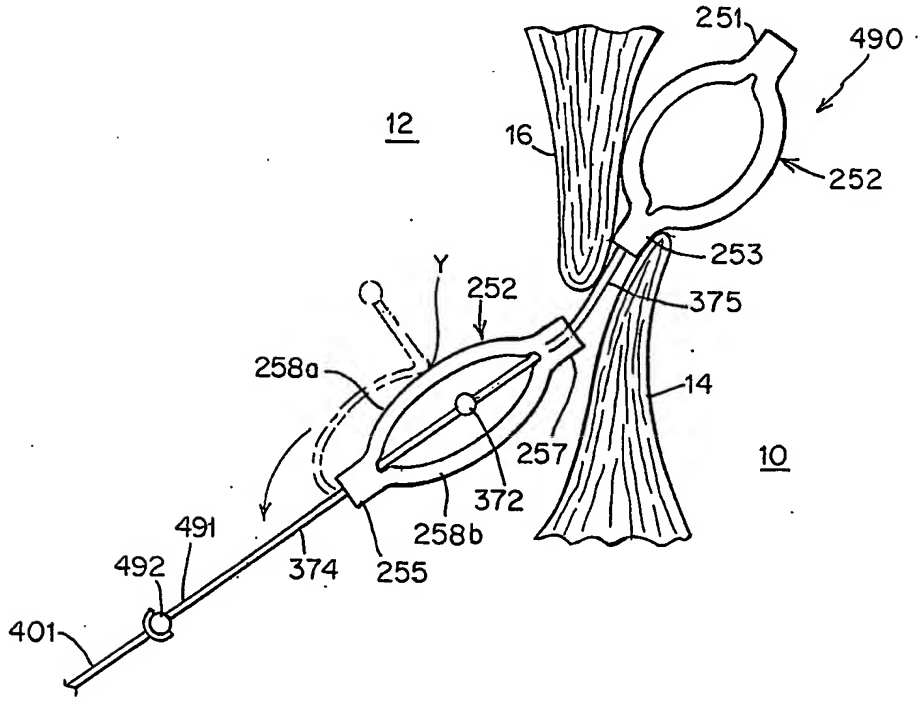
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FIG. 51

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/029978

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/171774 A1 (SIEGNER GEORG ET AL) 11 September 2003 (2003-09-11)	1-9, 15-17, 19-23, 27-31
Y	paragraph '0067! - paragraph '0069!	12-14, 32-35
	paragraph '0077!	
Y	WO 03/053493 A (NMT MEDICAL INC) 3 July 2003 (2003-07-03) claims 21-24	12-14, 32-35
A	US 6 419 669 B1 (VAN DER BURG ERIK J ET AL) 16 July 2002 (2002-07-16)	1-9, 12-17, 19-23, 27-35
	column 14, line 66 - column 15, line 25	
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
14 January 2005	26/01/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Angeli, M

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/029978

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 117 159 A (BUSCEMI PAUL J ET AL) 12 September 2000 (2000-09-12) column 6, line 40 - column 7, line 6	1-35

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/029978

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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